Performance Review of Canadian Blood Services

Final Report

October 15, 2002

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i. Executive Summary

In 1998, Canadian Blood Services (CBS) assumed management responsibility of the national blood system from the Canadian Red Cross. The initial challenge facing this organization was to ensure a safe and secure blood supply and to restore public confidence in the blood system. The mandate of CBS is described in a Memorandum of Understanding (MOU) that was signed by representatives of all of the provinces/ territories (except Quebec). The MOU established the roles and responsibilities for the key stakeholders in the national blood system: the federal government, the provincial/ territorial governments and CBS. The MOU outlines the functions to be provided by CBS and a set of principles to guide operations and decision-making.

Core Operational Functions

- Donor recruitment and management
- Whole blood and plasma collection
- Testing and lab work
- Processing
- Storage and distribution
- Inventory management

Key Support Functions

- Standard, policy and guideline setting supplementary to any regulatory standards of the federal, provincial or territorial governments
- Coordinating a national program in research and development for blood, blood products and transfusion medicine
- Surveillance and monitoring
- Professional and public education and information
- Health risk management.

Guiding Principles

- The safety of the blood supply is paramount
- A fully integrated approach is essential
- Accountabilities must be clear
- The renewed blood system must be transparent
- Voluntary donations should be maintained and protected
- National self-sufficiency in blood and plasma collections should be encouraged
- Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged
- Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained
- A cost-effective and cost-efficient blood supply program for Canadians should be encouraged.
- A national blood supply program should be maintained.

The MOU also includes a provision for a review of the national blood authority within five years of its creation to determine if it has "adequately fulfilled its functions and responsibilities..." The review was commissioned by the provincial/territorial ministries of health (with BC Ministry of Health as the lead Ministry) and was conducted from April to August 2002. The terms of reference for the review include a financial review, an operational performance review and a risk management review. Key components of the review methodology were:

- Stakeholder interviews
- An international benchmarking survey
- A hospital survey
- An analysis of financial statements
- An information technology assessment
- Documentation review

Input from a panel of internationally recognized experts in blood operations was utilized throughout the review. Findings and preliminary recommendations were presented to CBS and the expert panel for validation and feedback prior to inclusion in this report.

A summary of the key findings and key recommendations is provided below:

Achievements

Four years after its creation, CBS has evolved from the crisis phase through a stabilization phase and is now in the midst of a major organizational transformation process. The crisis is over. Stakeholders and the general public feel that the blood supply is safe. A Winter 2002 public survey found that 81% of respondents agree that "the blood system in Canada is safer today than it was five years ago". Other important accomplishments CBS has achieved include:

- Transforming a fragmented, decentralized blood supply program into a functional, national, blood system
- Achieving high donor satisfaction
- Enhancing the regulatory environment and framework
- Meeting regulatory requirements
- Increasing collections significantly
- Introducing new safety measures (e.g. universal leukoreduction, NAT testing)
- Implementing or upgrading various infrastructure systems.

Governance

CBS has a two-tiered governance structure consisting of the CBS Board of Directors and the Corporate Members who are the Provincial/Territorial Ministers of Health. The MOU sets out the mandate, roles and responsibilities for the Board and the Members.

The Board of CBS is committed and brings a wide variety of important skill sets to their role. They are evolving from the very hands-on role that was required when CBS was created to a more strategic mode of operation. Mission, vision, value and quality statements have been developed for the organization. Appropriate standing committees are in place including a National Liaison Committee with representation from several consumer associations. Attendance at Board and Committee meetings is excellent. Steps that would strengthen the board even further include:

- Implementation of a formal board evaluation process
- Clarification of the role of regional directors
- Development of a stakeholder communications strategy; including protocols for communication with provincial/territorial/federal officials
- Recruitment of board members with expertise in information technology, corporate law and haematology.

Two important responsibilities of the Corporate Members as set out in the MOU are to provide a policy framework for CBS planning and decision-making and to provide funding for CBS operations. There are concerns related to both of these roles. First, the policy framework has never been developed. As a result, there is a lack of guidance and context for CBS decision-making on policy issues. Also, the Corporate Members do not have a reference point against which to measure and assess CBS decisions. Progress on some important issues has been hindered by the lack of a policy framework. Some of the issues that would benefit the most from a national policy framework are:

- How to balance safety and affordability including what level of safety is appropriate for Canadians and at what costs
- The respective roles of the provincial/territorial ministries of health and CBS with respect to utilization management strategies for hospitals and physicians; this is required to control costs
- Plasma self-sufficiency

Corporate Members should develop a policy framework for the national blood supply system. The Members should also initiate a process for ongoing policy forums involving provincial/territorial governments, federal government, CBS, hospitals, physicians, consumer associations and researchers. There is also a need to review the MOU and improve its clarity in order to provide additional guidance.

The Corporate Members make the decision about how much funding to provide to CBS based on information supplied by CBS in their multi-year budget submission. The multiyear budget process has been time consuming, frustrating and ineffective. This is discussed in more detail in the financial review section. A contributor to the problems with the multiyear budget process is the fact that the relationship between CBS and the Corporate Members has been strained throughout most of CBS' four-year history.

Also, Members and CBS spend very little time in direct, face-to-face dialogue. While there is unanimous agreement that the relationship is improving, there is also agreement that there is a long way to go. These tensions have inhibited good, clear communication. Members do not always feel they get the information they need to make budget decisions and sometimes there is a lack of confidence in the information that is provided. CBS does not always feel they get appropriate policy direction.

There is a need for a vision for CBS that is shared between CBS and the Corporate Members. Although CBS has a vision statement and a transformation plan, there is a lack of a common understanding of where the organization is going, particularly as it relates to CBS' Transformation project and emerging trends and issues such as utilization and plasma self-sufficiency.

Regulatory Framework

In Canada, blood has been considered a drug since 1988 and is subject to regulations under the *Food and Drug Act*. Since the Krever Commission, Health Canada has strengthened its regulatory role in relation to the blood system. CBS is regulated by the Blood Establishment Regulation Division (BERD) of Health Canada. Each blood centre and CBS head office is audited by Health Canada once per year. Standard operating procedures (SOPs) must be documented in detail. New and revised SOPs must be approved by Health Canada. This process can be time consuming. Health Canada can also direct that certain safety procedures be adopted by CBS. Failure to comply with Health Canada regulations can result in loss of CBS' operating license.

A concern is that compliance with Health Canada regulations often has cost implications that must be absorbed by the provinces/territories. Some costs are direct costs such as the $35 per bag increase in the cost of blood bags when universal leukoreduction was mandated. Other costs are indirect such as the staff time involved in writing and revising SOPs and dealing with Health Canada on SOP changes. As CBS and the Corporate Members strive to predict and control rising costs, they must find a way to take the impact of the regulatory environment into account. Each party has a role to play in this. When the regulator dictates operational changes, CBS should produce an analysis that describes the costs, benefits and risks of the change, identifies the fit with international best practices, identifies alternatives, and highlights the implications for CBS. This analysis should be shared with the Members and the Provincial/Territorial Contacts. If the Members have concerns about implementing the change from either a cost, benefit or risk perspective, they should initiate a dialogue with the regulator to address these concerns.

There are some changes currently underway with respect to the regulatory environment. Health Canada is developing a new regulatory framework that will improve efficiency, speed and adequacy of the regulatory process. The purpose is to ensure the safety of the blood system without placing an undue burden on either the regulator or CBS. CBS is also in discussion with the regulator about ways to minimize the number of SOPs and to ensure that approval of new SOPs occurs in a timely manner. CBS must ensure that the Members are kept abreast of these changes.

Management Structure, Staffing and Service Delivery

As of March 2002, CBS employed 4,756 people across the country and had a volunteer base of 17,000. Leadership is provided by an Executive Management Team (EMT) that includes a Chief Executive Officer, three executive vice-presidents, three vice-presidents and an executive director of policy and planning.

The majority of CBS staff are affiliated with the 14 regional centres across the country. Each regional centre is headed by a "Centre Director" and a management team. Each Centre also has a Medical Director (part time) that provides medical leadership. Reports suggest that in the past each of the centres functioned quite autonomously. CBS is attempting to improve standardization. It is critical that these strategies continue expeditiously. A major concern in this regard is the existence of thousands of Centre Operating Procedures (COPs). COPs must be consistent with the Standard Operating Procedures developed by Head Office and approved by Health Canada and must be approved by both the Centre Director and the Centre's Quality Systems Associate that reports to Head Office. However, they are specific to each Centre and Head Office has no consolidated information on how many COPs there are and for what subjects. This situation does not provide assurance that, in keeping with being a national system, the same procedures are in fact followed consistently across the country.

Another issue that should be addressed from a service delivery perspective is patient services. Some Centres provide a variety of services to hospital patients but there is no consistency across the country in terms of what patient services are provided. This is a concern because CBS reports that the full costs of providing patient services are not recovered (direct costs are identified and recovered but the associated administrative and overhead costs are not identified) and therefore these services are partially subsidized by Blood Operations.

Transformation

CBS is an organization in transition. From the time CBS took over the operations of the Red Cross the need for substantial organizational and service delivery improvements was identified. The "Transformation Project" is now underway. It consists of several initiatives that touch upon all of the core functions. The initiatives are aimed at increasing donations, improving quality, improving automation and improving efficiency and cost-effectiveness. Initially, 28 different projects were identified by CBS. The following seven projects have been highlighted by CBS as priorities:

- Implementation of the MAK Progesa system

- Creation of a National Donor Contact Centre
- Consolidation of Testing Centres
- Consolidation and Specialization of Production
- Implementation of a Change Control System
- Unrelated Bone Marrow Donor Registry
- Implementation of SAP HR/Payroll (this project went live July 1, 2002)

A description of each of the seven priority projects is included in the report.

Managing a restructuring initiative of this nature is a challenge for a new organization. CBS needs to improve the management of the transformation project including:

- Improving the communications related to the project, particularly for the provincial/ territorial representatives many of whom lack a solid understanding of what is being done, when, why and at what cost
- Implementation of a rigorous program management methodology, including an integrated project plan
- Ensuring that comprehensive business cases are developed for each initiative
- Implementation of an organization-wide change management program for staff and volunteers.

Financial Cost Analysis

The total operating cost for CBS in 2001/02 was approximately $687 million. (This does not include approximately $103 million for fractionated products purchased for Hema-Quebec. These costs are fully recoverable from Hema-Quebec.) The operating budget for CBS has increased significantly each year since the organization was established. The increases are described as significant because they are much higher than the increases experienced in other parts of the health care system. From 2000/01 to 2001/02, total CBS operating costs increased by 13%. By comparison, Canada's health care sector experienced growth of 4.3% in 2001 however, other blood systems experienced similar growth rates to that of CBS.

The financial component of this review aims to provide a detailed description of the cost variances, identify the reasons for the variances and offer some commentary on the reasonableness of the cost variances. The detailed analysis is included in Chapter 2 of the report.

The review looked at each of the following business areas separately because they have different cost drivers: Blood Operations, Patient Services, Fractionated Products, Unrelated Bone Marrow Donor Registry.

Blood Operations expenditures have increased each year. In 2001/02, Blood Operations expenditures were $351 million, a 14.7% increase over the previous year. The main cost drivers for Blood Operations are:

- The demand for blood products (the volume of blood components shipped to hospitals increased by 5.3% from 2000/01 to 2001/02; the units of blood (all components) collected by CBS increased by 7.1%)
- Salary costs, which reflect provincial collective bargaining agreements (CBS reports that the average annual salary increase is approximately 4% per year but can range from 1% to 10%)
- The regulatory environment that can impact labour hours and/or medical supply costs (e.g. manual expiry date labelling resulted in an increase of 32 FTEs; leukoreduction increased the cost of blood bags by approximately $35 each which had a direct impact on the cost per unit of blood collected)

Expenditures increased in all areas of Blood Operations. The largest dollar increases were in whole blood collections, quality assurance and quality control and administration/overhead.

Expenditures for whole blood collections increased by $8.9 million or 10%. This is a reasonable reflection of the 7.1% increase in the volume of collections and salary cost increases.

Donor recruitment costs increased by 16% and recruitment costs per unit of whole blood collected increased by 7%. To ensure cost-effectiveness, donor recruitment should be monitored closely from the perspective of costs versus outcomes/benefits.

Expenditures for quality assurance and quality control (QA/QC) increased by $6.3 million or 62%. CBS attributes the cost variance to two initiatives – the Change Control Initiative and the System Wide Validation Initiative. For the Change Control Initiative, professional fees and travel costs were $2.3 million and $284,000 respectively. For the System Wide Validation Initiative, professional fees and travel costs were $1.3 million and $293,000 respectively. These costs are relatively high and should be monitored for cost-effectiveness and because once these projects have been completed a reduction in QA/QC should be observed. Labour costs for quality assurance and quality control increased by $1.8 million or 21%.

From 2000/01 to 2001/02, total administration/overhead expenses increased by $6.6 million. Combined administration/overhead for the national level and the regional centres was $85.4 million in 2001/02. This represents 24% of Blood Operations expenditures. This is a high proportion of administrative/overhead expenses and steps should be taken to reduce these expenses to the 10 to 15% range.

From the perspective of the total Blood Operations budget, there has been little variance between the budget and the actual results for Blood Operations. In 2001/02, CBS was under budget by $10.4 million and in 2000/01 they were over budget by $1.3 million. However, closer examination shows an opportunity for improved demand forecasting and budget management at the regional centre level. For 2001/02, the regional centres and the plasma centres had a combined negative budget variance of $8.6 million. Thirteen out of fourteen regional centres and both plasma centres were over budget in 2001/02, despite the fact that they used fewer FTEs than was budgeted and some reported efficiency gains.

Blood Operations is the core business of CBS and as such a better understanding of the cost of producing each type of blood product is required. At present, CBS reports a crude estimate of cost per unit of red blood cells but this indicator does not reflect the true costs. Also, cost per unit indicators are not reported for the other blood products such as platelets and plasma.

Patient Services accounted for $11.3 million or one percent of the total CBS budget in 2001/02. Patient Services includes a range of tests performed for hospital patients rather than blood donors. Each service is priced according to a fee schedule for billing purposes however, the fee schedule does not capture indirect overhead costs (e.g. administrative support in the centres, facility charges, finance and IT support from head office) or capital costs. CBS is encouraged to continue the examination of its role in the provision of patient services and analyzing the costs of providing these services.

Fractionated Products include a range of products derived from the various proteins found in plasma. The process of fractionation isolates and extracts specific proteins from pools of plasma. There are also some fractionated products that can be manufactured and are not derived from human plasma. These are called "recombinant" products. There has been a high demand for recombinant products because of the perception that they are safer than plasma-derived products.

Canada does not have a fractionation plant. Therefore, most fractionated products are purchased from American suppliers. The supplier ships the product from the U.S. to the CBS fractionated product warehouse in Ottawa. The warehouse then ships the products to each of the 14 Centres. The Centres ship the products to the hospitals along with their order of blood components.

CBS purchases Fractionated Products for Hema-Quebec and other customers. These costs are fully recoverable.

In 2001/02, CBS expenditures on Fractionated Products were $313 million. This represents an increase of 11% or $31.5 million over the previous year. The three main cost drivers for fractionated products are: the US/Canadian exchange rate, the cost per unit of fractionated products that is driven by market forces and the demand for fractionated products which is driven by hospitals, physicians, consumers and health care policy. Overhead costs account for $5.2 million or approximately 1.6% of total fractionated costs (including Hema-Quebec costs).

Management of the Fractionated Products part of the organization poses a number of challenges for CBS. First, product prices have been increasing at a significant rate.

Second, product utilization by the provinces/territories has been increasing. Both of these factors contribute to overall cost increases and CBS feels they have little or no control over the cost drivers. However, CBS should explore opportunities to influence prices through contract management and to influence demand through utilization guidelines and education.

A second issue is that actual expenditures on Fractionated Products have exceeded budget for the past couple of years. The variance was $16.5 million in 2001/02 and $34.2 million in 2000/01. However, when CBS original forecasts are compared to the member-approved budget and the actual expenditures, the analysis demonstrates that the CBS forecasts of fractionation expenditures are a relatively good predictor of actual fractionation expenditures. Original CBS forecasts come within less than $10 million (approximately 3%) of actual expenditures. However, due to funding constraints, the provinces and territories typically approve a budget that is less than the amount requested by CBS based on their forecast. The variances between the Member approved budget and the actual expenditures is much greater than the variance between the CBS forecast and the actual expenditures. These results underscore the importance of the provinces/territories and CBS working collaboratively to set realistic and evidence-based budget goals.

A third, and extremely important, concern related to Fractionated Products is working capital. A significant proportion of CBS's cash is tied up in inventory. At the time of this review, CBS reported inventory of $78 million. Of that $78 million, $64 million consists of fractionated products and approximately $10 million consists of medical supplies. Approximately $3 million of the inventory is Whole Blood.

When CBS was created in September 1998, a total of $27 million was provided to cover the cost of inventory for fractionated products. This figure has not changed over the last four years. The levels of inventory (i.e. number of weeks supply of product) that CBS maintains also has not changed in four years. Because the demand and cost of fractionated products has increased significantly, there is an inventory coverage shortfall. CBS must use $37 million from its cash reserves to finance the unfunded portion of the fractionated inventory. Recently, CBS has resorted to the use of "Restricted Funds" to fund this $37 million dollar shortfall.

The current working capital situation is a serious issue and it should be the number one priority addressed by CBS and its funders at this time.

The Unrelated Bone Marrow Donor Registry (UBMDR) accounted for $9.4 million in expenses in 2001/02. This represents a budget variance of $1.9 million and an increase of $1.1 million over the previous year's actual. It should be noted that UBMDR revenue is also above plan by $1.4 million, which partially offsets the $1.9 million variance. Approximately $4.9 million revenue is generated under the UBMDR program. UBMDR revenues are obtained by charging other blood organizations for performing donor searches. UBMDR expenses are all of the expenses incurred for managing the registry. This includes all labour, medical supply and other costs. Under the current funding model, any variance between the revenue and the expenses must be funded from Blood Operations.

UBMDR expenses have been steadily increasing over the past few years. Based on this trend alone a continued increase into 2002/03 would be projected. However, this trend may be offset (in whole or in part) by the impact of a new bone marrow registry system that was implemented in June 2002. The new system is expected to reduce the effort and costs of the search process. CBS has initiated a UBMDR Audit to understand and match their costs against the sources of revenue. They are currently in Phase I of the audit and are working towards allocating costs in the most appropriate manner as well as providing a detailed price analysis.

Multiyear Budget Submission

CBS is required to submit a three year corporate plan and a one year budget to its Members. CBS budgeting begins with forecasts of the units of blood to be issued to hospitals served by each Centre. The SAP system is used for development of the budget except for the salary information. Preparing the multi-year budget submission is a long process which takes CBS approximately ten months. The process has been affected by the strained relationship between CBS and the Corporate Members, particularly when it comes to financial issues. Corporate Members and P/T Contacts feel that CBS has not always provided them with the information they need to support decision-making on the budget and corporate plan. CBS feels that the information needs have not always been clearly spelled out but that they have responded appropriately to specific information requests.

There is no mutually agreed upon template for submission of the multi-year budget submission and CBS would develop the format for submission. A review of the most recent corporate plan suggests many areas for improvement. The plan was not particularly user-friendly. The narrative component was lengthy and information was provided without a context in terms of Member decision-making needs. Financial data was included in an appendix at the end with minimal explanation of the financial figures which were often confusing. In the past, the information needs of the Members were communicated in a reactive fashion. That is, a set of questions and requests for clarification would be prepared after the initial submission had been presented. In June 2001, the Provincial/Territorial Blood Liaison Committee prepared a "Checklist for Consideration in Ongoing Budget/Business Planning Processes" that provides very specific guidance for the content of the multi-year budget submission. This report includes a suggested template for the multi-year budget submission as well as several specific recommendations to improve the process.

Information Services

The Information Services (IS) department is a centralized support function operating out of CBS' Lancaster Road location in Ottawa. The IS department is managed by a Chief Information Office (CIO) who reports up through the Vice President of Corporate Services/CFO. IS employs approximately 133 staff which are a combination of CBS staff and contracted consultants. The total operating budget for IS is $14 million with an additional $28 million being allocated to four transformational initiatives (e.g. MAK implementation, Centralized Contact Centre, Consolidated Testing, and UBMDR)

CBS has aggressively moved to centralize the management of technology infrastructure from the IS location. The IS department has adopted an agile approach to Information Technology strategy which allows it to update its plan annually. CBS' IS department has also successfully employed technology portfolio management as a planning and budgeting tool. CBS' IT strategic approach allows for a better focus on CBS operational drivers as its projected time horizon is not excessively distant, and the portfolio management approach allows it to align IT spending with overall CBS business drivers.

The information technology systems at CBS are not leading edge. This has been recognized by CBS and that is why a number of Transformation initiatives focus on improving technology and automation. In particular, the introduction of MAK Progesa is expected to address many of the shortfalls in the current systems. Some additional opportunities for improvement include:

- Review PC platform financing options and explore staggering its capital purchase or leasing with its current hardware vendor
- Implementation of a chargeback or cost allocation mechanism for telecom and office equipment costs incurred by various departments.
- Consider the creation of a central IS project management office to centrally manage the multiple issues and dependencies that the many proposed initiatives are expected to create; this would include a review of the change management and training plan.
- The current burden of five and seven part regulatory approvals for all changes to the BLIS and FPMS systems is burdensome. CBS and Health Canada should explore the creation of a pre-approved procedure for break, fix and maintenance procedures.
- Consider eliminating the PDSI system and include the donor scheduling and call list generation capabilities into the ESS system until the Central Contact Centre and CRM initiatives are complete.
- Revise the resource scheduling model to reflect actual clinic capability.
- Explore the use of mobile technologies or the expansion of remote access capabilities as part of the replacement of PDSI.
- Explore a system that would allow telemarketers to solicit potential donors if a clinic is closer to their home than one they have used in the past.

- Review the SAP licensing agreement and continue to benchmark per seat costs against other Ottawa companies and government organizations.
- Continue to explore aggressive enterprise re-pricing contracts that allow for tiering of user types as additional modules are considered.
- Consider the implementation of employee time-entry as a next-stage project for SAP.

Operational Performance

CBS has made substantial progress in implementing performance indicators that focus on the four priority areas for the organization: enhance customer service, improve quality and safety, increase cost-effectiveness and greater employee satisfaction. There are two levels of performance measures: corporate measures and operational measures. Corporate measures were introduced by CBS in September 2001 and the operational measures in April 2002. However, at this stage, it appears that the implementation of the operational performance measures is further ahead than implementation of the corporate measures. Targets have been established for the operational performance measures but not for all of the corporate performance measures.

The performance measurement process was too new to support an adequate assessment of its effectiveness but there was evidence that the performance measurement program has been disseminated widely throughout the organization, is being used by the Centres and has been well-received.

This review assessed CBS performance relative to the ten guiding principles set out in the MOU. A summary of this assessment is provided in the table below:

Guiding Principle	Achievements	Areas for Improvement
The safety of the blood supply is paramount.	• New donor screening questions have been added • Donor deferral policy for vCJD has been implemented • Universal leukoreduction has been introduced • Two new tests (NAT-HCV and NAT-HIV) have been introduced to detect Hepatitis C and HIV earlier than with traditional testing • Manual expiry date labelling has been introduced • Quality Systems Department is in place • Most stakeholders and the general public feel that safety has improved	Need to review the cost-effectiveness of NAT testing in light of the actual number of "window" cases detected and recently introduced royalty costs.
Adequacy and security of supply of all needed blood, components and plasma fractions	• Volume of blood collected has increased every year since 1998 • 83% of hospitals reported that order lead times meet their requirements	• Hospital issues have not kept pace with the volume of collections; CBS has not met its target in terms of

Guiding Principle	Achievements	Areas for Improvement
for Canadians should be encouraged. A national blood supply program should be maintained.	• Bi-weekly fractionated products update is issued to all Centres, hospitals and Health Canada • 80% of hospitals reported their satisfaction with acquisition of fractionated products to be "very good" or "good" • Each Centre has a Service Interruption Recovery Plan • A contingency fund is in place for emergencies	meeting hospital demand • The target for meeting hospital demand should be more ambitious • Elective surgeries have been cancelled as a direct result of a blood product shortage; this indicator should be tracked by all hospitals and reported to CBS
A national blood supply program should be maintained.	• Blood is regularly imported/exported to different provinces based on need • Standard Operating Procedures are developed at the national level • A number of support functions have been centralized nationally (IT, payroll, purchasing, marketing, communications) • Some national strategies have been developed by Head Ofice • Plans are in place for consolidation of a number of core functions including testing, manufacturing and telerecruitment	• Degree of variation among Centres should be addressed (e.g. variations in services provided, existence of a large number of Centre - specific operating procedures)
A fully integrated approach is essential.	There is a need to clarify the definition of this principle.	
National self-sufficiency in blood and plasma collections should be encouraged.	• Canada is self-sufficient in red blood cell collections and platelet collections	• Plasma collections are less than 30% of the nation's requirements • The location of the two plasma centres should be reviewed in terms of critical mass and viability • A clear policy on plasma self-sufficiency is required
Accountabilities must be clear.	• CBS demonstrates accountability to Members through annual submission of a 3 year corporate plan and budget • CBS complies with Health Canada regulations	• There are ambiguities in the MOU • There is a lack of consistent understanding of the roles of the Corporate Members and CBS
The system must be transparent.	• CBS has a National Liaison Committee with consumer representation that reports to the Board • Two open board meetings are held each year • Board minutes and audit results are	• Information sharing is based on a "public relations" model whereby the decision about which information to share publicly is still largely made by CBS.

- Review the SAP licensing agreement and continue to benchmark per seat costs against other Ottawa companies and government organizations.
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Guiding Principle	Achievements	Areas for Improvement
	posted on the CBS website • Consumer associations have been consulted on relevant policy issues • CBS meets with the National Blood Safety Council and participates in their forums.	
A cost-effective and cost-efficient blood supply program for Canadians should be encouraged.	• Mandatory appointment booking for donors so that clinic activity is more predictable • A standardized clinic model • Centralization of key support functions such as information technology, finance, payroll and purchasing • Tracking of operational performance measures and comparing these metrics across the various Centres • Bloodmobile pilot underway • Plans developed for: MAK Progesa system to automate many information management functions that are currently done manually; PRISM technology to replace traditional testing for enzyme linked immuno-assay with a less labour intensive process; Consolidation of testing from 11 laboratories to three laboratories; a National Contact Centre to replace the decentralized donor telerecruitment function	• Costs per unit should be calculated for all blood components not just red blood cells • CBS has not met its target to reduce the cost per unit by 5% • Labour hours per unit varies significantly across Centres • Administrative overhead costs represent a relatively high proportion of total expenditures • The wastage rate for blood bags is approximately 5% • Discard rates are high for all blood components (based on both expert opinion and CBS' own targets) • Consideration should be given to CBS' role in facilitating inter-hospital transfer of blood products to minimize hospital discard rates for outdated blood products • Sole supplier contracts should be re-examined • Utilization management guidelines for fractionated products are required
Voluntary donations should be maintained and protected.	• All donations are voluntary • Donations have increased over the years • Donor satisfaction is monitored regularly and a Donor Advisory Panel is in place	• There is a need to increase the percentage of the eligible population that are donors (current rate is 3.6%)
Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained.	Currently blood is free to all recipients that are covered by Canada's health insurance program	

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Risk Management

Risk Management mechanisms are systems within CBS that control risk, provide monitoring, feed information back to management, and allow for change within the risk management architecture. They include:

- Member reviews
- Board oversight
- Management oversight
- Regulatory oversight
- Insurance
- Emergency Response
- Competency profiles of employees
- External accreditation
- Courses and training
- Change Control Operating Procedure

While the organization has had informal risk management capacity for some time (as described above), the capacity for formal, structured risk management is still being put in place. As the first of four phases of implementing risk management, a plan for roll-out has been developed. Recent changes include the development of the framework, dedicating staff to risk management, separating Quality Assurance from manufacturing, and planning for risk management training of key staff. The second phase, "Development", is in progress. A number of initiatives are under development, including the completion of a Risk Management Manual. It is noted that implementation is behind the schedule set in the Risk Management Program Update in February of 2002. This is an area of concern. Although the delay may simply be attributed to ambitious planning that did not factor delays into the timelines, it may also suggest that risk management is having difficulty competing for resources within the organization.

As mandated by the MOU, the Board of CBS has approved a framework to guide risk management at CBS.[1] It sets out the objects of the corporation as set out in the Letters Patent. It also provides references to materials and literature used to develop the framework. This framework is structured, comprehensive and focused on the needs of the particular organization. It follows a logical sequence. A number of specific suggestions to further improve the framework are included in the report. It must be noted that the Risk Management Framework does not specifically resolve the governance issue concerning the importance of safety.

As part of the assessment, documentation of a few recent and significant CBS decisions was reviewed to determine if risk management was integrated into the decision making process. The decision regarding consolidation of testing to three existing laboratories was reviewed most comprehensively. Overall, the review showed that risks were comprehensively considered, analyzed, and factored strongly in these decisions.

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[1] It is understood that this policy is currently under revision.

Opportunities for improvement to the risk management function include:

- Provide clarity in governance (i.e. the MOU)
- Rationalize Risk Management Policies
- Rationalize Risk Management Tools and Framework
- Apply the Framework Early and Often
- Exercise Discipline in Applying Frameworks and Tools
- Develop a Common Risk Management Language
- Provide leadership and change management support for implementation
- Build Risk Management into continuous learning
- Improve the systems to support the processes
- Continually improve the Risk Management Framework.

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CBS has come along way in its short, four-year history. Many board members and staff commented that the situation they inherited was worse than they thought. There were lots of bridges to build and fences to mend but more importantly there was a great deal of work for the new leaders to do. What did not take long however, was the process for the leadership to understand the mandate of the organization and to embrace the concept of "safety is paramount" that has come to characterize CBS in the eyes of many stakeholders.

This review found an organization in which board members and executive leaders are committed to the success of the organization. Although the review did not include many opportunities for contact with frontline workers, when board and management were asked to identify the strengths of the organization, the frontline staff was the most common response. Clearly, CBS is evolving and will soon be "transforming" as it attempts to keep pace with international best practices in blood operations.

CBS' ability to achieve its Transformation objectives and to continue to satisfy the terms set out in the Memorandum of Understanding will depend on its ability to address a number of issues.

In the coming months, it will be important for CBS and the Members to develop an action plan for moving forward with the suggestions emanating from this review. It is suggested that once the urgent financial matters have been resolved that role clarification, visioning and cost saving opportunities take precedence. This should be followed by a review of the MOU with a view to updating the MOU to reflect the current realities and future directions.

A summary of all of the review recommendations is provided in section 7 of the report.

1. Study Background

1.1 Origin of Canada's Blood System

Canadian Blood Services (CBS) was established in 1998 but the history of Canada's blood system dates back over 50 years. An understanding of the evolution of the blood system is helpful to understanding why CBS exists and the challenges it faces today.

Throughout the two World Wars, the Canadian Red Cross functioned as an auxiliary to the medical services of the Canadian Armed Forces; they collected blood from volunteers and shipped the whole blood to the University of Toronto's Connaught Laboratories for processing. Over time and as the number of volunteer donations began increasing, the Red Cross took on some of the blood processing functions. By 1947, the Red Cross had established a national blood transfusion service that was providing whole blood free of charge to hospitals. With advances that were being made in Transfusion Medicine and transfusion technologies, these previously simple donor and transfusion services became increasingly complex and expensive to maintain. The Red Cross needed capital funding to continue operating their Centres.

In 1958, the Red Cross began to receive some financial support from the federal and provincial governments for their blood transfusion service, while the Red Cross retained responsibility for full funding of their blood donor programs. By 1973, the financial support from both levels of government for blood transfusion services reached 90 per cent; and in 1977, the provincial governments took over full financial support for transfusion services and 80% of blood donor recruitment services within their respective provinces.

The Red Cross budgets then became subject to review by government representatives. In 1976, the federal Minister of National Health set out three governing principles for the Red Cross blood supply system:

- voluntary donation,
- national self-sufficiency, and
- gratuity of blood products to recipients.

In 1979, the provincial Ministers of Health endorsed these principles and added a fourth:

- desirability of non-profit domestic fractionation.

By 1979, the Red Cross was operating 17 blood services Centres across the country.

What was not included with these principles were definitions of the respective roles of the Red Cross, as the operator of the system, and of the provinces and territories, as the funders of the system and the users of blood products.

During the 1980s, the federal, provincial and territorial funding for the Red Cross was administered by the Canadian Blood Committee (CBC). Because the CBC had no corporate existence of its own and was not independent of governments, it was unable to make decisions that would bind the governments it represented or grant approval for annual budgets. New safety measures required the approval of every province and territory. Further complicating the speed and appropriateness of decision making was the lack of clarity regarding where the respective authority of Red Cross and CBC began and ended and communication issues.

In 1991, the Canadian Blood Agency (CBA) was formed as a federal, not for profit corporation through which the provinces and territories would fund and direct the blood system. Throughout this time, the Red Cross was also undergoing major organizational change.

A May 13, 1993 report entitled "Tragedy and Challenge: Canada's Blood System and HIV" said that the Canadian blood system "did not respond to the HIV/AIDS challenge as quickly as it might have" but was unable to determine the reasons for this delay. The Standing Committee on Health & Welfare, Social Affairs, Seniors, and the Status of Women recommended a comprehensive review into the Canadian blood system and on September 16, 1993, the federal, provincial and territorial governments (excluding Quebec) recommended a public inquiry be held. On October 4, 1993, Justice Krever was appointed to carry out this review.

In February 1995, the Krever Commission presented an Interim Report on the safety of the blood system which reported a need for the blood system to be restructured to eliminate conflicts among the participants and to define clearly the responsibilities for the safety of the blood supply. In September 1996, Canada's Health Ministers met and deliberated on the complex issue of blood system reform and agreed to put in place a new national authority to operate Canada's blood system based on four principles:

1. Safety of blood is paramount;
2. A fully-integrated approach is essential;
3. Accountabilities must be clear;
4. The renewed blood supply system must be transparent.

In addition, the seven ministerial principles defined by the provincial and territorial Ministers of Health in 1989 were added to complement the above principles:

1. Voluntary donations should be protected;
2. National self sufficiency in blood and plasma collections should be encouraged;

3. Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged;
4. Safety of all blood, components and plasma fractions should be paramount;
5. Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained;
6. A cost effective and cost efficient blood supply program for Canadians should be encouraged; and
7. A national blood supply program should be maintained.

These principles were to guide the provincial and territorial governments throughout the period of planning and transition to the new system that would ensure the safety of the Canadian blood supply.

1.1.1 The Creation of the Current National Blood System

On September 10, 1996 the federal, provincial and territorial governments created a national blood authority that was to operate at arm's length from all governments and would be responsible for managing all aspects of an accountable blood system. The province of Quebec had already chosen to opt out of a national blood system and establish its own blood system called Hema-Quebec. October 15, 1997 saw the appointment of Canadian Blood Services Transition Bureau whose mandate was managing the safe and effective transfer of the Canadian Red Cross Blood Program to the new national blood authority, Canadian Blood Services (CBS). CBS was incorporated in February 1998 and CBS' Board of Directors assumed responsibility for the transition in April 1998. CBS assumed full responsibility for the operation of the blood system on September 28, 1998.

The scope of services (core functions, key functions and responsibilities) of this national blood authority were set out in the 1997 *Federal / Provincial / Territorial Memorandum of Understanding (MOU):*

Core Operational Functions:

- Donor recruitment and management
- Whole blood and plasma collection
- Testing and lab work
- Processing
- Storage and distribution
- Inventory management.

Key functions to support these core operational functions, were to include:

- Standard, policy and guideline setting supplementary to any regulatory standards of the federal, provincial or territorial governments
- Coordinating a national program in research and development for blood, blood products and transfusion medicine

- Surveillance and monitoring
- Professional and public education and information
- Health risk management.

In addition, CBS is under the regulatory purview of the *Food and Drugs Act*.

The MOU also includes a provision for a review of the national blood authority within five years of its creation to determine if it has "adequately fulfilled its functions and responsibilities and to consider such modifications to the present Memorandum as they may deem necessary to remedy any possible deficiencies." This statement is the foundation for the review that is the subject of this report.

1.2 Project Overview

1.2.1 Study Purpose and Objectives

Acting as the lead province on behalf of the provinces and territories (excluding Quebec), the British Columbia Ministry of Health Services issued a Request for Proposal (RFP) for a "full and comprehensive review of the current and projected activity of Canadian Blood Services (CBS) as it relates to the Memorandum of Understanding between CBS and the Provinces and Territories" (the Members). The purpose of the review was to provide the Members and the CBS with options and recommendations for action and direction in relation to the current budget submission process.

The RFP required the following matters to be reviewed:

1. Financial review and review of the scope of operations:
   a) Analyze the current status of CBS financial performance, with reference to the level of services provided.
   b) Review scope and definition of core operations including:
      i. Core services indicated in Annex A of the MOU including their importance to the provision of blood supply on a national basis.
      ii. Provision of key support functions as indicated in Annex A of the MOU, and
      iii. The relevance and costs of the current non-core functions and services.
   c) Identify opportunities for operational efficiencies that would result in cost savings.

2. Performance review:
   a) Undertake a comparative performance review
      i. Assess the comparative standings of CBS financial and operational performance, as compared to Héma-Québec and blood suppliers in other countries with a similar service level, using a set of financial and operational performance indicators.

        ii. Review performance indicators
            01. Identify current performance indicators and review them for completeness and relevance.
            02. Recommend additional performance indicators.
    b) Review risk management functions
        i. Identify and assess risk management mechanisms as they relate to the safety, affordability and adequacy of the blood system.
        ii. Provide recommendations for improvement based on the assessment of the mechanisms identified.

3. Based on the above analysis, examine the current content, format and process of the multi-year budget submissions and make recommendations for improvements that will ensure timely, adequate and appropriate information is provided to the Members and CBS.

4. Identify regulatory and manufacturing industry cost drivers and their impact on the blood system.

1.2.2 Study Approach and Methodology

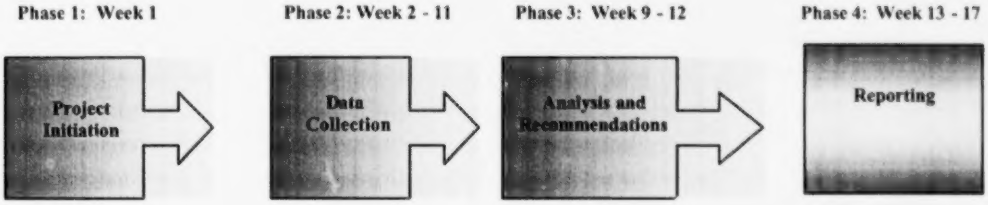
In planning the approach and methodology for this study, the goal was to ensure that the review is successful, practical and provides meaningful information to support decision-making.

Accessing blood system expertise was considered critical to the review. Dr. Thomas Zuck was engaged to be part of the consulting team and provided ongoing advice and input throughout the project. In addition, the BC Ministry of Health assembled an international Expert Panel to provide advice on the project methodology, the international benchmarking survey, the study findings and the draft recommendations. The members of this panel were Dr. David Pi, Ann Hoppe and Dr. Richard Counts. Dr. Zuck also participated in all Expert Panel meetings.

It was important that the review be more than a report card on the past. To be most valuable, the review recommendations should prepare CBS and the provincial/territorial governments not only for the current environment but also for the future.

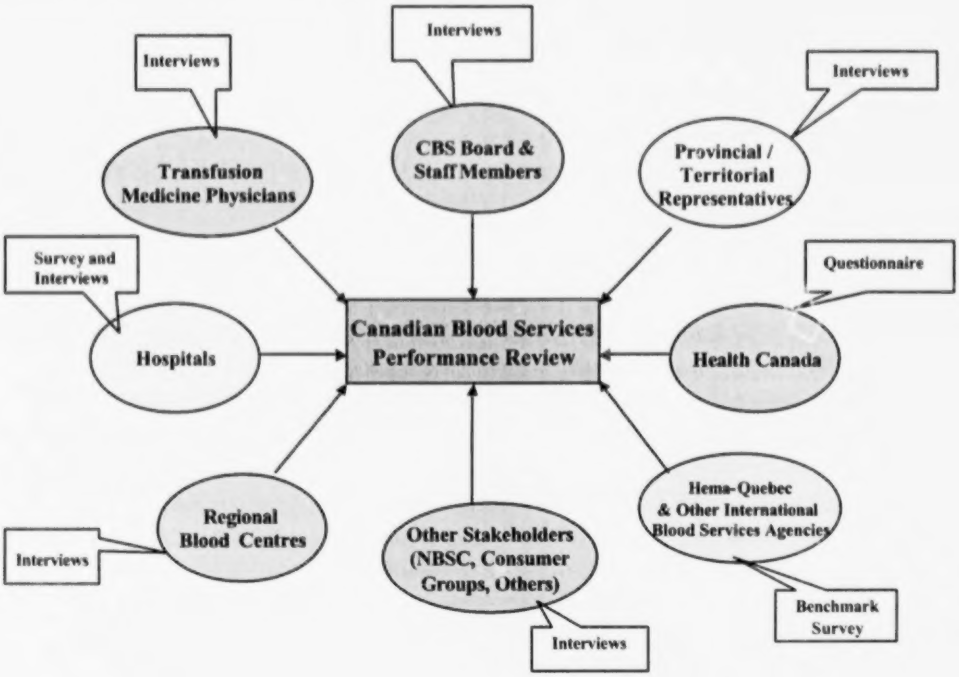
The project methodology was divided into four phases:

Exhibit 1-1: Project Phases


Phase 1: Week 1
Phase 2: Week 2 - 11
Phase 3: Week 9 - 12
Phase 4: Week 13 - 17
Project Initiation
Data Collection
Analysis and Recommendations
Reporting

Given the number and diversity of stakeholders of CBS, it was important that a comprehensive data collection approach be established early on in the project. A project evaluation plan was developed to guide the review. The following diagram highlights the variety of data collection sources and tools used to conduct the review. A brief description of the major information collection strategies follows.

Exhibit 1-2: Information Collection Methods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Interviews
CBS Board & Staff Members
Interviews
Provincial / Territorial Representatives
Survey and Interviews
Hospitals
Canadian Blood Services Performance Review
Questionnaire
Health Canada
Regional Blood Centres
Interviews
Other Stakeholders (NBSC, Consumer Groups, Others)
Interviews
Hema-Quebec & Other International Blood Services Agencies
Benchmark Survey

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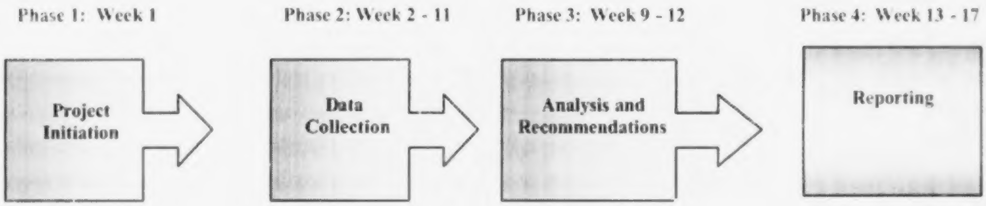
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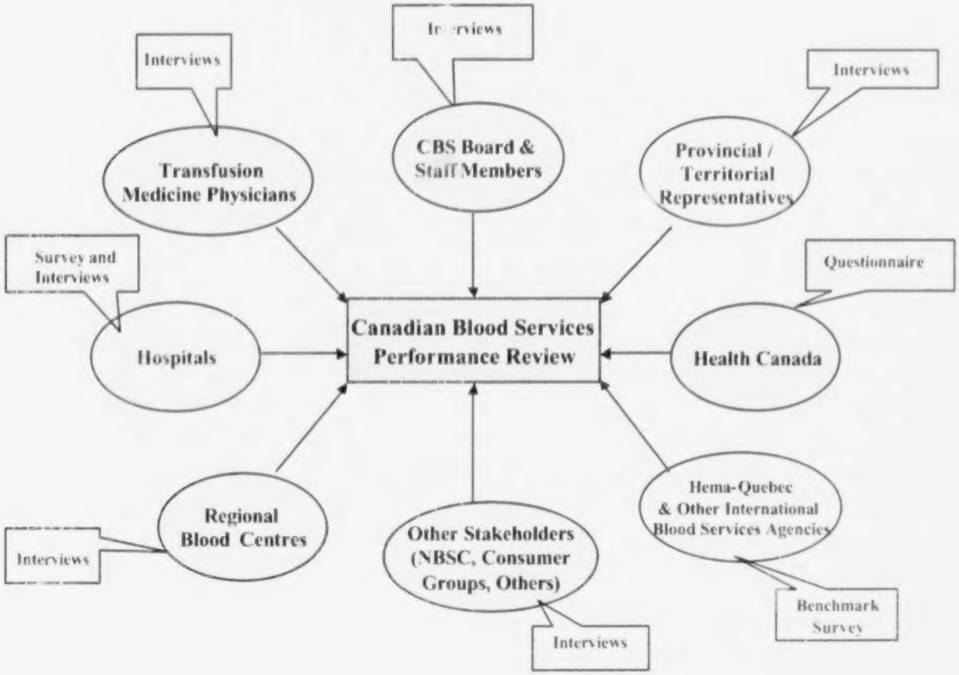
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Health Canada
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Interviews
Interviews
Benchmark Survey

Financial Review

The objective of the financial review was to understand the financial components of CBS's core operations, key support functions and non-core functions and services. This consisted of analyzing CBS's external and internal financial statements, interviewing personnel in the finance departments as well as personnel outside of the finance departments who have direct or indirect influence on the budget.

Document analysis involved developing an understanding of the trends observed in the financial statements. Interviews were conducted with senior finance staff to further understand the implications and the justifications for the major changes in the financial statements. Document requests were made to further breakdown the different expenses by category, thereby allowing key cost drivers to be identified, and understanding the impact of those cost drivers.

An analysis was produced and the preliminary findings and recommendations were discussed with the Chief Financial Officer to help explain any inaccuracies or inconsistencies in the report to ensure that there were no misunderstandings in the financial analysis prior to the finalization of this report.

Key documents reviewed are listed in **Appendix A.**

IT Assessment

A very high-level assessment of information technology capabilities at CBS was conducted. This task was a late addition to the initial project scope and therefore did not commence until mid-July. The assessment was based on interviews with senior IT staff, a visit to the Ottawa Centre for user input and documentation review. A list of the documents reviewed for the IT Assessment is included in **Appendix A**. A list of the staff interviewed is included in **Appendix B.**

The preliminary observations and recommendations from the IT Assessment were discussed with the Chief Information Officer prior to finalization of this report.

Documentation Review

To support our review activities, we identified and requested information that would best help our team quickly understand the scope and functions of CBS. A list of the documents reviewed is provided in **Appendix A**.

Stakeholder Interviews

Interviews were used as one method for identifying information and gathering opinions, perceptions and attitudes. Our team conducted approximately 70 interviews with representatives of the following stakeholder groups:

Current and Past CBS Representatives:
- CBS Board members
- Current CBS executive and management staff
- CBS Regional Centre Directors and Managers
- Past CBS Chief Executive Officer
- First CBS Board Chair

Federal and Provincial Government Representatives:
- Provincial/Territorial Contacts
- Federal and Provincial Deputy Ministers or delegates

Hospitals:
- Vice-Presidents of Medicine and Laboratory Directors

Medical / Transfusion Specialists:
- National Technical Working Group on Utilization Management
- National Blood Safety Council

Consumer Groups:
- Canadian Haemophilia Association
- Canadian AIDS Society
- Hepatitis C Society
- Canadian Medical Association

An interview guide was prepared for each group of stakeholder interviews and provided to participants in advance. The overall objectives of the individual interviews was to obtain information that will allow an assessment of the performance of CBS and opportunities for improvement. A list of stakeholders interviewed is provided in **Appendix B.**

International Benchmarking Survey

As specified in the RFP, an international benchmarking survey was conducted to assess the comparative standings of CBS financial and operational performance, as compared to Hema-Quebec and blood suppliers in other countries with a similar service level, using a set of financial and operational performance indicators.

The international agencies were selected based on selection criteria agreed upon by the *Ministry and the Consultants with input from CBS. The Consulting team's* recommendation on the countries to participate in the survey was reviewed by an international Expert Panel selected by the BC Ministry of Health.

The survey was designed to collect the following types of information:

- Profile information about the country's health care system and the blood agency in order to understand similarities and differences to CBS that should be taken into account in the analysis
- Types of standards used
- Financial indicators (i.e. cost by activity level)
- Operational performance indicators

The Consultants developed the survey questionnaire with input from CBS and the Expert Panel. Detailed instructions and definitions for calculating financial and operational performance indicators were also prepared in conjunction with CBS and provided to the participating countries. A copy of the questionnaire is included in **Appendix C.** The questionnaire was distributed via e-mail to a designated contact person in each country selected. The Expert Panel assisted the consultants in identifying contact persons in the selected countries.

The criteria considered in selecting the international cohort were:

Similarity to the Canadian Blood System

- The blood system is voluntary
- The volume of blood collected is comparable to CBS volumes
- The size and nature of the geographic area covered by the blood service is similar to the area covered by CBS (e.g. land area, rural/urban, transportation issues)

Similarity to the Canadian Health Care System

- A significant public health insurance program is in place
- The size of the adult population is similar to the Canadian population

Assurance of Quality Standard

- The blood service is accredited by a recognized program

Ease of Information Collection

- The extent to which individuals involved in the review have contacts in the country that can facilitate information collection

The above criteria reflect the ideal. However, it quickly became apparent that there is no other blood system exactly like CBS and this would be an unrealistic expectation. There was also a recognition that valuable learnings can result from studying blood systems that have taken different approaches to organizing and operating their system.

Based on the selection criteria, the decision was made to send the survey to Hema-Quebec and the following five international blood agencies:

- American Red Cross
- Australia
- France
- Sweden
- United Kingdom (England and North Wales)

Survey responses were received from:

- Canadian Blood Service
- Hema-Quebec
- Sweden - Uppsala and Orroro county
- United Kingdom (England and North Wales)
- The American Red Cross

CBS and Hema-Quebec completed the full survey whereas the other countries provided partial responses only. A follow-up telephone conversation was conducted with a Hema-Quebec representative to better understand some of the responses submitted. The survey results were also supplemented to a limited extent with publicly available information on other blood service agencies. (However, it is important to note that a literature review was not within the scope of this study.) A brief summary of the blood systems in the participating countries is provided in **Appendix D.**

Hospital Survey

A hospital self-administered survey was developed to achieve the following objectives:

- To give hospitals an opportunity to provide input into the review
- To understand hospital requirements for blood components
- To assess hospital satisfaction levels with the provision of blood components
- To identify opportunities for improvement

The survey addressed issues related to: demand planning, order and inventory management, performance measurement and customer service. A copy of the survey tool is provided in **Appendix E** and detailed results are provided in **Appendix F**. The survey was developed by the Consultants. A CBS Centre Laboratory Director with hospital blood bank experience and a member of the Expert Panel reviewed the draft survey before it was finalized.

The survey was distributed to hospitals between June 20 and June 24 by means of e-mail or fax. Using mailing lists supplied by CBS, surveys were sent to the identified hospitals' laboratory/blood bank managers for completion. The deadline for return of the surveys was July 10.

A total population of 556 hospitals in all provinces and territories excluding Quebec, were identified as receiving red blood cell shipments from CBS in 2001/02. Small and remote hospitals that receive their blood components from larger hospitals with no direct shipments from the CBS were excluded from the sample.

Sampling quotas were established to ensure representation from each province and territory based on the number of hospitals directly serviced by CBS. For the smaller provinces and territories (Nova Scotia, New Brunswick, Newfoundland, P.E.I., Yukon, Northwest Territories, Nunavut), all hospitals receiving CBS products were surveyed. A sample of approximately 60% was drawn from the remaining larger provinces with special attention paid to including the hospitals that receive the largest volumes of blood shipments.

A total of 387 hospitals were sampled. This represents 70% of all hospitals that receive CBS shipments. Assuming an expected 40% response rate, this sample size would ensure 95% statistical validity with a 5 to 7% confidence interval.

221 completed surveys were returned - a response rate of 57%. The table below shows the number of surveys distributed and returned by province. Some hospitals did not answer every question on the survey. The findings presented in this report include the number of responses on which the results for each question are based.

Exhibit 1-3: Hospital Survey Sample and Returns

Province	Hospitals That Receive CBS Shipments	Hospitals Surveyed	Hospitals That Returned Surveys	Survey Response Rate
British Columbia	88	66	43	65%
Alberta	67	43	33	77%
Saskatchewan	76	52	27	52%
Manitoba	72	40	27	68%
Ontario	166	106	46	43%
New Brunswick	22	22	15	68%
Newfoundland	28	20	8	40%
Nova Scotia	22	22	14	63%
PEI	8	7	2	29%
Yukon	1	1	1	100%
Northwest Territories	4	4	3	75%
Nunavut	2	2	1	50%
TOTAL	556	387	221	57%

Note: One survey received was anonymous, accordingly the numbers in the column headed "hospitals that returned surveys" do not add up to 221.

Validation Process

Once all of the information collected had been analyzed, an important part of the methodology was validation of the findings and preliminary recommendations. Two validation sessions were held to confirm the accuracy and interpretation of the findings and to get feedback on the preliminary recommendations prior to submission of a first draft of the report.

The first validation session was held on July 23, 2002 with the senior leadership team at CBS. Participants in the all-day (9 a.m. to 3 p.m.) validation session were:

- Gary Chatfield, Board Chair
- Graham Sher, Chief Executive Officer
- Ian Mumford, Executive Vice-President Operations
- Wesley Rees, Executive Vice-President Safety and Performance Management
- Dana Devine, ExecutiveVice-President.P. Medical, Scientific and Clinical Management
- Watson Gale,Vice-President and Corporate Legal Counsel
- Darren Praznik, Executive Director Government Relations
- Pauline Port, Vice-President Corporate Services and Chief Financial Officer
- John Johnston, Vice-President Human Resources and Organizational Development
- Jeff Moran, Chief Information Officer
- Craig Ivany, Executive Director, Centre Operations
- Sophie deVillers, Executive Director, Policy and Planning
- IBM Business Consulting Services Team Members: Rik Ganderton, Michele Jordan, Gail Peterson, Kelly Shum and Dr. Thomas Zuck

A second full-day validation session was held on July 26th with members of the International Expert Panel. Participants in this session included:

- Dr. Richard Counts, President, Puget Sound Blood Centre, Seattle, Washington
- Ann Hoppe, Regulatory Consultant, Decatur, Georgia
- Dr. David Pi, Director of the Provincial Blood Co-ordinating Office, B.C. Ministry of Health Services
- Wendy Trotter, Manager, Blood Services, B.C. Ministry of Health Services
- IBM Business Consulting Services Team Members: Rik Ganderton, Michele Jordan, Gail Peterson, Michael Matthews and Dr. Thomas Zuck

Two draft reports were submitted for review by various provincial/territorial representatives and CBS. The feedback received has been incorporated into the final report.

1.2.3 Study Limitations

A number of factors had an impact on the methodology and/or outcomes of the study. It is important to describe these factors upfront so that they can be taken into account when interpreting the study results.

Study Scope and Objectives. The study was a performance review aimed at assessing the financial and operational performance of CBS. It is also important to clarify what the study was not.

- The study was not an accreditation or inspection of CBS from a safety, regulatory, clinical or technical point of view.
- The study was not a financial audit.
- The study was not a detailed examination of each service delivery and administrative function.

Study Timeframe. The timelines for the study were established at the outset by the BC Ministry of Health. The study commenced at the end of April and had a firm date of August 1 for submission of the draft final report. This allowed three months for project start-up, data collection, analysis, recommendation development and report writing. The tight study timelines placed limitations on the type and number of data collection activities that could be conducted. It was extremely important to clarify the project scope in terms of what could be done within the timelines (see above) and what the focus would be. It also necessitated a sufficiently large team to get the job done within the required timeframe.

Another important aspect of the study timeframe was that it included the summer months. This posed a challenge for scheduling interviews with stakeholders and conducting surveys.

The project timelines had a significant impact on the international benchmark survey. A number of countries noted that they would have preferred more time to answer the questions (e.g. three months was suggested by one country) and that vacation schedules (particularly in European countries) limited the availability of staff to gather the data.

Financial Data. At the time of the data collection phase of the review, the final audited financial statements were not available. Therefore, some of the statistics contained in the report for fiscal year 2001/02 were from unaudited sources. Also, for many areas, it was only possible to examine changes over the last two fiscal years. This is due to a number of organizational changes and modifications to the accounting methodology at CBS.

Risk Management Assessment. The terms of reference for the project called for the Consultants to:

"Review risk management functions

- Identify and assess risk management mechanisms as they relate to the safety, affordability and adequacy of the blood system.
- Provide recommendations for improvement based on the assessment of the mechanisms identified."

It is important to stress that the project scope did not include an assessment of the risks faced by CBS or the adequacy of the risk management function. The review of risk management functions focused on the structure and process of risk management mechanisms. There was no attempt to identify and assess actual risks or to comment on the outcome of specific risk issues.

Impact of Transformation. While the performance review was being conducted the CBS was in the midst of a major Transformation project which includes several initiatives touching almost all aspects of the organization. For the most part, the initiatives are in the early phases of implementation and are not yet in place. This posed a challenge for the review team because the organization under review was clearly in a state of evolution. Also, a number of the areas identified for improvement were reportedly to be addressed in the future by the Transformation project, potentially rendering some of the review recommendations redundant. Without the ability to assess the success of the Transformation initiatives, the review was limited to assessing the extent of due diligence to support the transformation projects (e.g. existence of business cases, cost analysis, priorization criteria, project plans, etc.).

2. Organization and Service Review

2.1 Historical Context and Highlights

CBS is a not-for-profit, charitable organization whose mission is to manage the blood supply in all provinces and territories (excluding Quebec). It was incorporated in February 1998 and took on the responsibility for Canada's blood system on September 28, 1998.

CBS has had to stabilize and operate the system, and is only now catching up to developments in international blood systems management.

CBS inherited an organization consisting of three levels of management: central, regional and local.

At the Central or Head Office level, corporate functions and services are offered such as developing national standards and support services. Functions such as payroll, human resources and accounts payable occurred at the regional level. Once the transition from the Red Cross to CBS took place, these regional services were targeted for transfer to the Head Office.

The local level is currently comprised of 14 Blood Centres and two Plasma Centres. The Blood Centres are located in Vancouver, Calgary, Edmonton, Regina, Saskatoon, Winnipeg, Toronto, London, Hamilton, Sudbury, Ottawa, Halifax, Saint John, Charlottetown, and St. John's. The Plasma Centres are located in Thunder Bay and Charlottetown.

Each of these Centres performs many similar tasks: donor recruitment, blood collection, testing, production, storage and distribution of blood. In addition to these core services, some Centres offer specialized services such as stem cell extraction, prenatal testing, and transmissible disease testing.

At present, the organization has approximately 4,700 staff and 17,000 volunteers. Operating expenditures for the organization have risen steadily over the years and are now over $750 million. Donors and collections have also increased. There are over 465,000 active donors in CBS' database. In 2001/02, over 803,000 units of whole blood were collected. CBS supplies blood to approximately 550 hospitals across the country.

The initial challenge facing this organization was to ensure a safe and secure blood supply and to restore public confidence. Fundamental to how CBS was to achieve this was how the new organization would be managed. Key aspects of the organizational structure include:

- An independent Board of Directors, appointed by the Members, and who represent stakeholder interests.

- Independent expert advisory committees whose role is to provide early and informed reviews to the CEO:
    - Research & Development Advisory Committee
    - Scientific Advisory Committee
    - Consumer Advisory Committee (later changed to the National Liaison Committee)

- Transparency with respect to CBS operations, including:
    - Two public Board meetings per year
    - Regulatory audit results posted to CBS' web site
    - General information available on the web site
    - Stakeholder consultation and input for decision making

- A contingency fund that allows CBS to respond to unforeseen events in a timely and flexible manner

2.2 Achievements

CBS has come a long way in a short time. The organization that CBS inherited had a number of shortcomings. Several of these shortcomings are described in the Krever report:

The Red Cross, as the operator of the blood supply system during the 1980s, did not promptly introduce appropriate risk-reduction measures to enhance the safety of the blood supply. The internal structure of the Red Cross was not conducive to sound and timely decision making. The Red Cross adhered to principles that were not related to the blood supply system, and its board of governors supervised many programs that were not related to the blood program. The Red Cross's blood transfusion service and its blood donor recruitment each had partial management of the blood program. The national office of the transfusion service did not create and enforce comprehensive national risk-reduction measures, nor did it allow local centres to exceed the national safety standards that did exist. There were no formal links to the provincial public health authorities.[2]

The many significant challenges facing the new CBS leadership included overcoming internal organizational deficiencies, improving the safety of the nation's blood system, enhancing employee and volunteer morale and restoring public confidence in the blood system.

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[2] Krever Commission Report, Volume 3.

This context is critical to setting realistic expectations for the performance of CBS less than four years after its inception. Some of the many accomplishments CBS has achieved in its four-year history include the following:

- Transforming a fragmented, decentralized blood supply program into a functional, national, blood system
- Restoring public confidence in the blood system following the tainted blood crisis
- Achieving high donor satisfaction
- Enhancing the regulatory environment and framework
- Meeting regulatory requirements
- Increasing collections significantly
- Introducing new safety measures (e.g. universal leukoreduction, NAT testing)
- Implementing or upgrading information management systems (e.g. SAP, BLIS 2000, ESS)
- Centralizing the accounting function in Ottawa. This includes the accounts payable, purchasing, accounts receivable, general accounting and reporting.
- Introducing an organization-wide performance measurement framework ("Strategy Map")

The national crisis that precipitated the establishment of CBS was a public crisis. Therefore, the public's views on the current blood system are of special interest. CBS routinely commissions public surveys. The most recent survey found that 81% of respondents agree that "the blood system in Canada is safer today than it was five years ago." [3]

During the course of this review, many different stakeholders were consulted. When these stakeholders were asked to describe the strengths of the CBS there were several different responses but also some common themes.

Key strengths cited by the various stakeholder groups include:

- Dedicated staff on the frontline
- A strong senior management team ("They are enthusiastic, positive and are a good configuration of people and skills.")
- A committed board of directors
- Safety measures that have been implemented (" They've got their eye on the ball on safety – they've done an exceptional job of implementing safety precautions")
- A national system is now in place
- An approach that is proactive rather than reactive
- Public image and donor recruitment

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[3] Winter 2002 General Public Research Program, Final Report, by Ipsos-Reid Corporation, April 2002

- Good local collaboration
- Sound understanding of the main issues in the blood system, from both an academic and an operational perspective
- Monitoring, reporting and follow-up on directives
- System is more open and interactive

CBS is to be commended for its many significant achievements particularly providing Canadians with a safer blood system. There is no longer a crisis.

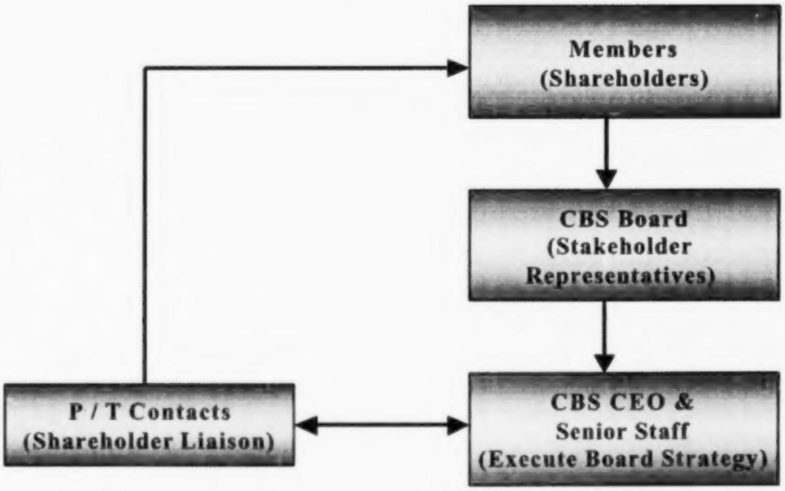
But, like any other organization, there are always things that could be improved. The balance of this report describes findings and observations and offers suggestions for improvement moving forward.

2.3 Governance

2.3.1 The Governance Structure

CBS has a two-tiered governance structure consisting of 1) the Corporate Members and 2) the CBS Board of Directors. This is illustrated in the diagram below. The Members are the Ministers of Health in the provinces and territories. The Members appoint the CBS Board of Directors to oversee the organization. Each Member has identified a contact person from their Ministry to serve as the day-to-day liaison with CBS. These individuals are collectively referred to as the P/T Contacts.

Exhibit 2-1: CBS Governance and P/T Liaison Structure


Members
(Shareholders)
CBS Board
(Stakeholder Representatives)
CBS CEO &
Senior Staff
(Execute Board Strategy)
P / T Contacts
(Shareholder Liaison)

The Federal/Provincial/Territorial Memorandum of Understanding

The mandate, roles and responsibilities for the Members and the Board are set out in a Memorandum of Understanding (MOU). The purpose of the Memorandum of Understanding "is to record the understandings and commitments of the Minister of Health (Canada) and the Provincial and Territorial Ministers of Health regarding their respective roles and responsibilities in a renewed national blood system, including their future relationships with the National Blood Authority [i.e. CBS] and its function and structure".

The MOU came into force in 1997 almost one year before CBS was established. When the document was written, the term "National Blood Authority" or "NBA" was used to describe the yet to be formed new blood agency.

The MOU is a critical document because it sets out the roles and responsibilities of the various levels of government and describes the mandate of the CBS. There are a number of annexes to the MOU:

- Annex A sets out the functions and responsibilities of the CBS
- Annex B describes the governance model
- Annex C addresses transition issues

Recognizing the importance of the MOU as a guiding document, it is used as the frame of reference for this review. That is, CBS' performance is assessed against the roles, functions and responsibilities described in the MOU.

The definition of the overall roles and responsibilities of the federal/provincial/territorial governments, as set out in the MOU, was to include:

- Funding
- Setting broad health policy objectives
- Serving as members of the national blood authority
- Ensuring the overall integrity of the blood system
- Exercising their on-going powers and responsibilities as Ministers under existing health legislation.

The roles and responsibilities of the federal government, as set out in the MOU, include:

- Responsibility for the administration of the *Food and Drugs Act* with respect to the national blood system
- Responsibility to ensure that Canada maintains an effective national blood system surveillance program
- Responsibility for regulating certain components of the national blood system

- Preparation of an annual report on regulatory policies and decisions in relation to blood
- Meet twice annually with the Members to discuss issues of mutual concern
- Provision of transition funding
- Provision of annual funding for research and development.

Overlaying these roles, responsibilities and functions, the MOU stated that the common policy objective for the new national blood authority would be based on the following principles:

- The safety of the blood supply is paramount
- A fully integrated approach is essential
- Accountabilities must be clear
- The renewed blood system must be transparent
- Voluntary donations should be maintained and protected
- National self-sufficiency in blood and plasma collections should be encouraged
- Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged
- Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained
- A cost-effective and cost-efficient blood supply program for Canadians should be encouraged.
- A national blood supply program should be maintained.

While the MOU provides some direction in terms of mandates, there are several sections of the MOU which are ambiguous and open to multiple interpretations. The most notable example of this relates to safety and affordability.

- Section 3.0 of the MOU states: "the *safety of the blood supply is paramount*".
- Annex B states: "The domain of management discretion will include matters of health and safety with respect to the blood supply system. Decisions in this regard will be made within a health risk management framework which *places on an equal footing the three critical elements of cost, benefit and risk*."

Other examples of ambiguities in the MOU that warrant clarification include:

- The MOU states "national self-sufficiency in blood and plasma collections should be encouraged". It is not clear what "encouraged" means and whether or not achievement of this principle is mandatory.
- Annex A lists a key function of CBS as "standard, policy and guideline setting supplementary to any regulatory standards of the federal, provincial or territorial governments". This is reinforced in Annex B with the statement: "the Board is responsible for development and implementation of NBA standards supplementary to any regulatory standards of the federal, provincial and territorial governments".

As discussed later in this report, CBS is of the view that supplementary standards are not necessary in the current regulatory environment. This view was not shared by the review's expert panel.

- Annex B states "NBA will own and operate the blood supply system". Annex B also states "NBA is the vehicle by which the provincial and territorial governments can deliver a national blood supply program…"
- Annex B states "NBA must be able to exercise complete management discretion over all operational blood system decisions" and "the mandate of the NBA is to be responsible for a national blood supply system…" Annex B also states "Canada's provincial and territorial Health Ministers will be responsible and accountable for the national blood supply program".
- Annex B mentions a "contingency fund for emergencies" but does not define an emergency.

These ambiguities contribute to a lack of role clarification amongst CBS and the Corporate Members.

Recommendation #1: The MOU is a critical guiding document for the national blood supply system. Unfortunately, the document includes a number of ambiguities that have contributed to lack of clarity in terms of roles and expectations. It is recommended that the Provincial/Territorial Ministers of Health and Health Canada initiate a process to clarify the ambiguities in the MOU and ensure that the current and future realities are reflected. A desired outcome would be a set of uniform priorities regarding safety, benefits and costs. If the relative weights of these factors are to vary depending on circumstances, these should be clearly spelled out. Ideally, the MOU review process should follow the proposed development of a vision (see below) so that the MOU is reflective of future directions. There are a number of optional approaches that could be taken: 1) the Members could initiate a review of the MOU and open a dialogue to change the wording of the ambiguous sections, 2) the Members could execute an addendum to clarify the ambiguous issues, or 3) some other form of common agreement between the parties could be reached to address specific issues that are currently unclear (e.g the policy framework might accomplish this). Reviewing and amending an inter-provincial MOU is a significant undertaking and the Members should seek legal advice on the most appropriate approach.

The Corporate Members

The Corporate Members are the Ministers of Health from each province/territory. As stated earlier, the Provincial and Territorial Health Ministers (excluding Quebec) are accountable for the national blood supply system. Their specific responsibilities were listed above.

The provincial/territorial Ministers are ultimately accountable for the national blood supply. The MOU describes the national blood authority as "the vehicle by which provincial and territorial governments can deliver a national blood supply program effectively and efficiently..."

The MOU recognizes that the Corporate Members wear two hats – they have responsibilities as Provincial and Territorial Health Ministers as Ministers and they have responsibilities as Members of the CBS. These dual responsibilities are described in the MOU as follows:

Exhibit 2-2: Dual Roles of Provincial/Territorial Health Ministers

As Provincial and Territorial Health Ministers	As Members of the CBS
"Ministers are responsible for: • the effectiveness of the blood supply system as an integral component of the P/T health care delivery systems • funding requirements of the NBA as approved by its Members • recommending to the Minister of Health (Canada) any proposed changes to the NBA legislation"	• Members establish and will remain responsible for the mission and mandate of the NBA • Members will have the authority to approve the three year corporate business plan • Members will be responsible for selecting the Board of Directors • Members have the authority to require direct external comprehensive management audits and targeted special audits of the NBA at their discretion • Should objectives for the blood program not be met satisfactorily, Members will hold the Board accountable to take corrective action • Members retain the power to remove some or all of the Board • Members will make available to the public the NBA annual report, including its audited financial statements

The duality of the Member/Minister roles challenges the Members/Ministers to fairly and effectively balance the needs of their particular province with the needs of the national blood system. An example of where this situation might pose a serious challenge is when CBS wishes to shift the provision of a particular function from one province to another province in order to consolidate/centralize the function and achieve efficiencies. While the efficiencies gained benefit CBS and ultimately the entire country, the consolidation process may result in loss of employment in the affected province.

The Provinces and Territories, through their Deputy Ministers, rotate the responsibility of the lead for the blood system every two years. Being the lead involves acting as a secretariat for all meetings and issues involving the blood system, and acting as the main liaison between the Provinces and Territories, and CBS.

CBS Board of Directors

The directors of CBS' board are appointed by the Corporate Members. There are 13 directors, including the Chair.

Composition. Four directors are considered "regional directors". Regional directors are elected on the basis of nominations from Members representing the regions of (1) British Columbia and Yukon, (2) Alberta, Saskatchewan, Manitoba, the Northwest Territories and Nunavut, (3) Ontario, and (4) New Brunswick, Prince Edward Island, Nova Scotia and Newfoundland.

Two Directors are elected from the general public on the basis of their relevant knowledge or experience with organizations representing persons consuming blood and blood products (i.e. consumers).

The remaining six Directors are elected on the basis of their knowledge or expertise with business, scientific, medical, technical or public health matters. Employees of the federal, provincial or territorial governments are not eligible for appointment.

The current Board members reflect a wide variety of important skill sets. However, interviews with Board members indicate that some Board members have identified a need for expertise in the following areas: corporate law, transfusion medicine and information technology.

Recommendation #2: Currently board members are selected based on geography as well as their expertise in business, scientific, medical, technical or public health matters. When filling future vacancies it is recommended that Members consider recruiting individuals with experience in corporate law, information technology and transfusion medicine.

One of the challenges facing the Board is their lack of clarity around the role of the regional directors. The MOU does not specify a particular role for the regional directors that is different from that of the other directors. However, one P/T Contact described the role of regional directors as "providing a voice on the Board that brings forward information about the interests, concerns and sensitivities of the Members of that region." Some regional directors have agreed to provide their regional Ministers with regular updates on the progress of CBS. At present this type of communication is carried out outside of the context of a broader communications strategy.

The question has also been raised about the need for the regional director positions. To provide a context for discussing this issue, a brief examination of the board composition of selected other national, health-related organizations was carried out. The table below illustrates the extent to which selected organizations have regional directors. A brief description of the mandate and budget of each organization is also provided.

Exhibit 2-3: Regional Directors – A Comparison of National Organizations

Organization	**Regional Directors (yes/no)**	**% Regional Directors on the Board**
Canadian Blood Service (CBS) Approximate budget - $750M	Yes	31%
Canadian Institute for Health Information (CIHI) An independent, non-profit organization that coordinates the development and maintenance of a comprehensive and integrated approach to health information for Canada and provides/ coordinates the provision of accurate and timely data and information. Approximate budget - $37M[4]	Yes	75%
Canada Health Infoway. An independent, non-profit corporation formed to foster and accelerate the development and adoption of electronic health information systems with compatible standards and technologies on a pan-Canadian basis. Approximate budget - $500M[5]	Yes	45%
Canadian Centre of Health Technology Assessment (CCOHTA) A non-profit organization that reviews research that has been done on medical technologies. Approximate budget - $3M[6]	Board consists of one representative from each province/territory and one federal representative	
Canadian Centre for Occupational Health and Safety	Yes	53%

The table above suggests that it is not unusual for national health-related organizations to have Board members that are appointed to represent a particular geographic region or a specific province. Clearly, national organizations find value in having Board members from various geographic regions. The issue for CBS is defining an appropriate role for regional directors and setting guidelines for Board member activities. CBS has struggled with this issue for a long time. For example, in 1999, the CBS Board required regional directors to submit written summaries of their interactions with their provincial ministers.[7]

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[4] Canadian Insitute for Health Information website (cihi.ca.)

[5] Canada Health Infoway website (canadahealthinfoway.ca)

[6] Canadian Centre of Health Technology Assessment website (ccohta.ca)

Compensation. Board members are compensated for their time. Reimbursement rates have been established for meeting time, preparatory time and travel time.

Roles and Responsibilities. The MOU describes the following responsibilities for the Board of Directors:

- Overall direction of the affairs, operational activities and budget of the NBA, including the appointment and dismissal of the Chief Executive Officer
- Translating the approved business plan into blood supply system operations
- Within the framework established by the Members, exercising broad discretion in establishing corporate and operational policies of the NBA, including setting and enforcing NBA standards
- Achieving the three-year corporate business plan
- Reporting on performance to Ministers as Members
- Developing and implementing NBA standards supplementary to any regulatory standards of the federal, provincial or territorial governments
- Developing corporate and operational policies
- Appointing committees as deemed necessary to help them in carrying out their duties
- The Finance Committee will be responsible for preparing NBA budgets for the approval of the Board

The Board of Directors of CBS was established before any staff were hired and before the organization was officially launched. At that time, there was a great deal of work to be done and even with the assistance provided by the "transition bureau", Board members were required to play an intensive, hands-on role. The Board remained in this very operational mode for most of the organization's short history with a focus on putting the required structures, systems and processes in place. In the past year, it appears that the Board's role has evolved in keeping with the maturing of the organization. There is now a concerted effort to shift the board to a more strategic mode of operation.

Committees. The board has established the following standing committees:

- Executive Committee
- Finance and Audit Committee
- Human Resources Committee
- Safety, Science and Ethics Committee

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[7] CBS Board Minutes of May 19, 1999.

There is also a National Liaison Committee. The National Liaison Committee was initiated as a pilot. The committee is made up of members of the public, stakeholders and the medical community at the national level. The purpose is to provide input on blood system issues, ensure special interests are brought to the attention of CBS, and to build effective relationships with stakeholders. The summary notes from these meetings are posted on the CBS Web site. The Chair and Co-Chair of the National Liaison Committee are the two consumer representatives on the Board of Directors. Over a dozen consumer associations are represented on the National Liaison Committee.

Attendance. CBS posts the attendance record for each individual board member on its public website. The Board of Directors held 37 meetings (full Board and various Committees) during the period April 1, 2000 to February 19, 2001. The results for this period suggest a board that is dedicated and involved.

There were ten Board meetings held during the period. Board meetings typically last two to three days. Fifty-eight percent of Board members attended all ten of the Board Meetings and another 25% attended 9 out of 10 meetings. Only two board members missed two or more Board meetings.

The attendance rates for Board Committee meetings are also quite high. Seventy-five percent of Board members attended 20 or more Committee meetings. The other Board members attended between 8 and 19 Committee meetings. Forty-two percent of Board members had a perfect attendance record for all Board and Committee meetings. These are very impressive attendance records.

Board Evaluation. CBS' Board has been carrying out informal evaluations since as early as 1998.[8] The decision to carry out a formal Board evaluation process was made at the October 17, 2000 meeting of the Executive Committee of CBS Board of Directors. It was agreed that an existing Board evaluation tool would be used for the first evaluation. A questionnaire was administered and the results were tabulated and discussed at the Executive Committee meeting on December 13, 2000. The results were generally positive. The Board Evaluation results were also reported to the full Board and results relating to specific committees were sent to the respective Committees for discussion. At the meeting of CBS Board of Directors held on September 20, 2001 a motion was passed "that the Board of CBS establish and implement a formalized Board Evaluation process in order to assess effectively the ongoing performance of the Board and its ability to achieve excellence in governance". At the time of this review, this "formalized" process had not yet been completed. However, in preparation for the last strategic retreat of the Board, one of the Board members developed a detailed questionnaire to gather information on the Board's views of the strengths and weaknesses of the organization. The questionnaire achieved a high response rate and the results were presented and discussed at the Board Retreat.

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[8] CBS Board Minutes, July 8, 1998.

Recommendation #3: It is recommended that CBS complete the proposed development and implementation of a "formalized" Board evaluation process.

CBS Corporate Statements

CBS has a number of corporate statements that provide parameters for its operation.

The Letters Patent was signed in February 1998 as part of the organization's application for incorporation of a corporation without share capital under the *Canada Corporations Act*. There are also seven by-laws. CBS has articulated mission, vision and values statements as follows:

Exhibit 2-4: CBS Mission, Vision and Values

Mission Statement
Canadian Blood Services operates Canada's blood supply in a manner that gains the trust, commitment and confidence of all Canadians by providing a safe, secure, cost-effective, affordable and accessible supply of quality blood, blood products and their alternatives.

Vision Statement

Canadians have **confidence** in us.

Canadian Blood Services provides a safe, secure, cost-effective, affordable and accessible supply of **quality** blood, blood products and their alternatives. Canada is self-sufficient in blood and we are working to be self-reliant in plasma. Emerging risks and best practices are monitored continuously. Our blood and blood products are safe and of quality.

CBS has established and works to maintain **effective** relationships with all of our stakeholders.

Our arm's length relationship with Provincial/Territorial and Federal governments enables us to operate within our business plan and with **reliable** funding. We are known for our financial stewardship of public funds.

We work with consumer groups to address strategic issues and meet their needs. We monitor our environment and other key indicators that enable us to **anticipate** changes and prepare for them.

CBS continues to help hospitals **improve** blood utilization and surveillance. We have found that educating consumers, donors, physicians and other health professionals is key to managing utilization of blood and blood products.

Donors actively support us and our donor base is **strong**. Our volunteers continue to play a **critical** and meaningful role.

Through our work and support, the science of transfusion medicine is **advanced**. Our research program is leading to the development of alternative products in transfusion practices.

We are internationally recognized for our **excellence** and innovative programs and services.

Our employees view CBS as a great place to work. We have an environment that **rewards** creativity, teamwork and vision, and provides opportunities for personal and professional advancement.

We are **proud** of the contribution we make.

Value Statements

We are committed to delivering safe, quality blood, blood products and their alternatives to Canadians through a national not-for-profit organization that:

- accepts responsibility for ensuring the safety and quality of Canada's blood supply system;
- considers blood a national resource;
- values and celebrates the contributions of blood donors and volunteers;
- values employees within an environment that provides opportunities for personal and professional advancement;
- encourages and welcomes early and informed input into its activities and operations;
- promotes the appropriate use of blood, blood products and their alternatives;
- responds quickly to medical, technical, scientific and management advances and innovations;
- accepts responsibility for the financial stewardship of public funds;
- rewards creativity, teamwork and vision;
- is guided by a code of ethical conduct;
- is value-driven and focussed on appropriate outcomes;
- is dedicated to achieving or exceeding world standards; and
- is dynamic, open and accountable.

Relationship between the Corporate Members and the CBS Board of Directors

The Corporate Members and CBS Board of Directors meet once per year as part of the Annual Meeting that is required by the *Canada Corporations Act*. The meeting is usually held in September and focuses on presentation of the budget and corporate business plan. The time period for these meetings is very limited – sometimes less than one hour.

To facilitate ongoing communication throughout the year, each province/territory has identified a staff contact person to serve as the liaison between CBS and the Corporate Members. These "P/T contacts" have fairly regular contact with CBS staff and meetings are held three or four times per year. They do most of the background work required to support effective decision-making by the Members. There is no common job description for the P/T Contacts and there are variations in their seniority, experience with blood issues, role and availability for CBS issues relative to other roles that they have within their Ministry. This leads to inconsistencies in the role performed. A basic job description should be developed which can be added to by each province/territory to reflect unique needs. The current P/T Contacts also bring a diverse range of skill sets (e.g. policy, finance, medicine) which is beneficial to the group as a whole and should be maintained.

The relationship between the Corporate Members and CBS' Board of Directors has been strained and difficult over the years. Members and P/T Contacts do not always feel that CBS provides all of the information they require for decision-making. CBS Board and senior management feel that Member information needs are not always well-articulated and that clear policy direction is sometimes lacking. Meeting the diverse needs of 12 independent jurisdictions combined with frequent changes in individual Corporate Members have heightened the communication challenge for CBS.

However, there is currently a consensus among the Members and P/T Contacts that communication has greatly improved within the last year. Provinces and territories are becoming more comfortable with the information that is being provided and there are reports that the overall relationship between CBS and the Members is much better. Recently, a mechanism has been put in place to allow for regular contact between the CEO of CBS and the Deputy Ministers of the provinces. The new Deputy Minister's Policy Committee on Blood is comprised of Deputy Ministers from British Columbia, Alberta, Manitoba, Ontario and Nova Scotia as well as the CEO of CBS. The Committee met once in June 2002 and are scheduled to meet again on October 30, 2002.

The limited amount of contact between CBS and the Corporate Members has meant a lack of opportunities for in-depth policy discussion. The MOU (Annex B) suggests that the Board of Directors must establish corporate and operational policies consistent with a policy framework established by the Members. Such a policy framework has not yet been developed. As a result, there are a number of outstanding policy issues that need to be addressed jointly by CBS, the Members and in some cases Health Canada. One example is plasma self-sufficiency which will be discussed later in this report.

Perhaps another symptom of the history of poor communication is the lack of a common understanding of roles and responsibilities. The MOU describes roles for the federal government, the provincial/territorial ministers and CBS but there are gaps in the descriptions and some statements are open to broad interpretation. Over the years, there has not been much progress in improving the clarity. As a result, the study found variations in how stakeholders perceive the roles of the various players. This includes the role of CBS, the Provincial/Territorial Ministers (as Ministers and as Members) and the P/T Contacts.

The issues described above in relation to role definition and a policy framework are critical to the effectiveness of the CBS. To demonstrate this point, one need only refer back to the Krever Commission Report which identified many of the same issues in relation to the Canadian Red Cross and the Canadian Blood Committee.

> *"In 1976, the federal and provincial ministers of health decided that the blood supply system was to be governed by three principles: voluntary donation, national self-sufficiency, and gratuity of blood products to recipients. The three principles did not begin to define the respective roles of the Red Cross, as the*

> *operator of the system, and of the provinces, as the funders of the system. In 1981, when the Canadian Blood Committee, whose members were public servant representatives of the federal and provincial governments, was formed, one of its tasks was to create a comprehensive national blood policy that defined the respective functions of the Red Cross and the committee. The committee never created a national blood policy. As a result, no one was clearly in charge of, or accountable for, the safety of the blood supply. The roles of the Red Cross and the committee were blurred, and the continuing tensions between them interfered with efficient and effective decision-making. The blood supply was consequently not as safe as it could and should have been. If the functions had been clearly defined, many of the problems relating to safety that arose could have been more quickly and effectively solved."*[9]

Clarification of roles and creation of a policy framework for CBS are priorities that the Members and CBS will need to address in a timely manner.

Recommendation #4: It is recommended that CBS develop a detailed Stakeholder Communications Plan that recognizes the Members as key stakeholders. The Stakeholder Communications Plan should include:

- A formal and ongoing government communication strategy that would include communications with the Ministers, Deputy Ministers, P/T Contacts, Federal officials and other key government stakeholder groups. This will be particularly important during implementation of the Transformation Project which will have varying degrees of impact on different provinces.
- Protocols for Board of Director communications with senior Provincial/Territorial officials. These protocols should take advantage of Regional Director reporting relationships and access to Ministers of Health. The communications protocols should also acknowledge that all CBS Directors should have access to Provincial/Territorial officials. The nature of the communication between regional directors and Ministers of Health should respond to the needs of the Ministers but would likely include updates on CBS issues and projects of interest to the Minister and solicitation of advice from the Minister on provincial factors to take into account in the corporate planning process. The protocols should also set expectations on the frequency of reporting to Ministers (e.g. twice per year).

Recommendation #5: The Annual Meeting between CBS and the Members is perhaps the single most important event for the CBS Board and EMT. Preparatory activities such as identification of coaches, intelligence gathering, identifying potential questions and hot spots, audience analysis, presentation skills, etc. are critical. The goal is for CBS to go to the Annual Meeting with a clear idea of the Members needs and armed with the specific information the Members require. Effective communication between

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[9] Krever Commission Report, Volume 3.

CBS and the P/T Contacts will provide advance notice of the interests and likely receptivity of Members to what CBS wishes to present and or have approved.

Recommendation #6: To improve communication between CBS and the Members, it is recommended that Members identify ways to expand the length of the meeting time with CBS and/or increase the number of meetings held per year. The recent establishment of the Deputy Ministers Policy Committee on Blood is a good start to building a better relationship.

Recommendation #7: It is recommended that the CBS Board and Corporate Members engage in a process to clarify the respective roles and responsibilities of Corporate Members (both as Members of CBS and as Provincial/Territorial Health Ministers), Deputy Ministers, the lead Ministry, P/T Contacts (a generic job description should be created), the CBS Board and the CBS Chief Executive Officer. This review of roles and responsibilities should give special consideration to clarification of roles and expectations with respect to utilization management. The statement of roles should emphasize a partnership between the Provincial/Territorial Ministers and CBS that recognizes that is the responsibility of the Ministers, not CBS, to manage utilization at the hospital and physician level. CBS can however, play an important role in research, education, guideline development and evaluation of utilization practices.

Recommendation #8: Discussions with stakeholders revealed a lack of a common view of where the organization is and should be heading in the future. It is recommended that the CBS Board and Corporate Members engage in a facilitated process to renew the CBS vision and describe the future role and scope of CBS. Clearly, there are a number of directions that could be pursued. Some of the directions that have been suggested by stakeholders include:

- Reduce size and scope of CBS to be strictly a producer and distributor of blood and blood components. This direction would consider such strategies as divesting the distribution of fractionation products, divesting patient services, outsourcing certain infrastructure functions (e.g. payroll, IT), shifting research and development and public education roles to other players, and leaving utilization issues to the provinces/territories.
- Enhance the size and scope of CBS through growth and diversification. Strategies that would take prominence with this direction might include working towards goal of plasma self-sufficiency, enhancing CBS' role in utilization management, increasing CBS' role in research and development and increasing CBS' technical leadership in transfusion medicine.

The vision must respond to the needs of the key stakeholders. It should reflect a customer-facing posture that places greater emphasis on utilization issues and hospital linkages. The review team does not support a reduction in scope that is based on divestment of the fractionation business because the MOU defines blood as including alternatives and commercial products. Also, it is not evident that there is an organization better equipped to take this on or that setting up a stand-alone fractionation operation would improve effectiveness or efficiency. Internal operations however, should be as lean and efficient as possible. As emphasized throughout this report, the review team favours an enhanced role for CBS in development of utilization guidelines and education initiatives.

Recommendation #9: The MOU implies that it is the responsibility of the CBS Board to develop operational policies within a framework established by the Corporate Members. The policy framework has never been developed and there have been few opportunities for productive policy discussion. Therefore, it is recommended that the Corporate Members initiate a process to create a policy framework that would guide policy development by CBS. The framework should include direction to CBS on how to balance safety and affordability in the blood system and what level of safety/risk will be acceptable for Canadians. Development of the policy framework should be informed by public dialogue, research and comparisons with blood systems in other jurisdictions.

Recommendation #10: It is recommended that Members request CBS to use a portion of their Research and Development funds to conduct research of a policy nature. For example, research on how other countries have dealt with key policy challenges such as balancing safety and affordability and establishing a level of risk tolerance.

Recommendation #11: It is recommended that CBS continue to convene regular (e.g. annual or semi-annual) forums to gather stakeholder input that will assist CBS in developing strategic policies. CBS has conducted forums in the past. The difference here is the link to policy development. CBS would be accountable for identifying a clear policy goal for each forum, disseminating forum proceedings in a timely manner and following through with policy development. Key policies would be submitted to the Members. Some of the pressing policy issues that should be considered include plasma self-sufficiency and utilization of fractionated products (particularly IVIG and Recombinant Factor VIII). It is important to note that a policy discussion on plasma self-sufficiency should be informed by a thorough identification and analysis of plasma costs (both production and purchase) and fractionated product utilization guidelines that will help to determine the level of demand that should be forecasted.

2.4 Management Structure and Staffing

As described earlier, the Canadian Blood Services Transition Bureau was appointed on October 15, 1997. The first Board, led by Chairman, Ken Fyke, was appointed in April 1998. The Board hired the first CBS Chief Executive Office (Lynda Cranston) who then hired an executive management team.

With some exceptions, the executive management team has remained intact but there has been some restructuring of executive management roles in an effort to streamline the executive team functions. For example, the former Vice-President Marketing and Communications and Vice-President, Operations positions are now a single position. Also, the Vice-President, Human Resources position has gone through some revision and is now responsible for Organizational Development as well as Human Resources. Another change was the creation of the position of Vice-President Corporate Services and Chief Financial Officer.

Last year, an important change in senior leadership occurred at CBS. Following the resignation of the Chief Executive Officer in July 2001, Dr. Graham Sher (past Vice-President, Medicine, Scientific and Clinical Management) was appointed as the new Chief Executive Officer. Ken Fyke ended his tenure as Chair of the Board in October 2000. William Gleed served as interim Chair between October 2000 and September 2001. Gary Chatfield was appointed as the new Board Chair in September 2001.

The current senior management of CBS is comprised of the following people and positions[10]:

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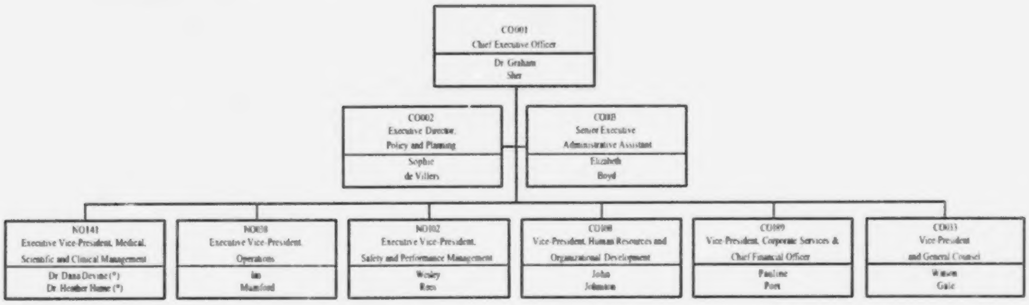
[10] CBS Organizational Chart, dated February 14, 2002

Exhibit 2-5: CBS Corporate Organizational Chart


CO001
Chief Executive Officer
Dr Graham Sher
CO002
Executive Director, Policy and Planning
Sophie de Villers
CO118
Senior Executive Administrative Assistant
Elizabeth Boyd
NO141
Executive Vice-President, Medical, Scientific and Clinical Management
Dr Dana Devine (*)
Dr Heather Hume (*)
NO038
Executive Vice-President, Operations
Ian Mumford
NO102
Executive Vice-President, Safety and Performance Management
Wesley Rees
CO108
Vice-President, Human Resources and Organizational Development
John Johnston
CO109
Vice-President, Corporate Services & Chief Financial Officer
Pauline Port
CO033
Vice-President and General Counsel
Watson Gale

Major Areas:
- R&D
- Transfusion Medicine
- Transmissible Diseases
- Laboratory Testing
- UBMDR

Major Areas:
- Centre Operations
- Manufacturing
- Donor Management & Recruitment
- External Communications & Public Involvement
- Communications

Major Areas:
- Quality Systems
- Regulatory Affairs
- Performance Management
- Program Development
- Audit
- Fractionation (interim)

Major Areas:
- Human Resources
- Education, Training & Organizational Development
- Occupational Health & Safety and Employee Wellness
- Employee and Labour Relations
- HRIS

Major Areas:
- Finance
- Facilities
- Information Services
- Supply Management

Major Areas:
- Legal Affairs
- Corporate Secretariat
- Government Relations

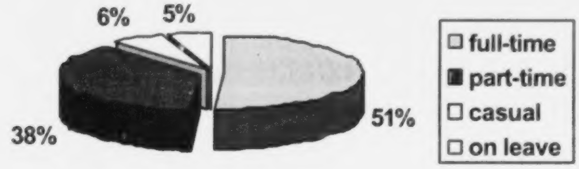
(*) = Acting capacity

2002-02-14

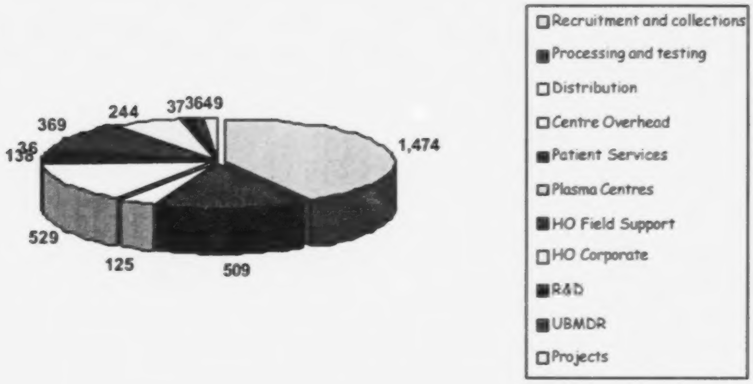
Currently, CBS employs approximately 4,756 people and has a volunteer base of 17,000. The following diagrams describe the total national workforce by work function.

Exhibit 2-6: CBS Workforce Statistics

CBS Workforce
•4,756 employees as of March 31, 2002



CBS Workforce - Number of FTEs by Key Function



In their efforts to increase overall organizational effectiveness, initiatives are being implemented under the Transformation Project umbrella that will have an effect on staffing levels. As CBS automates and standardizes work processes, introduces more technologies to manage work processes, consolidates activities and redesigns work functions, there will be a need for a different mix of staff and staff numbers required to collect and process blood and blood components. April 24, 2002 saw the public announcement of the multi-faceted Transformation Project whose full impact on staffing is not yet known. The Transformation Project is discussed in more detail in section 2.6.

As with other health care organizations, CBS will likely have to compete for human resources skilled in different areas such as information technologies. In addition, there will be a need to look at creative, innovative ways of making a highly regulated work environment an attractive alternative to other health care organizations. Maintaining human resources in the health care sector is a global issue and there are numerous sources of information on best practices in recruitment and retention that might be of assistance to CBS.

2.5 Service Delivery and Functions

Before describing the various functions provided by CBS, a brief orientation to blood and blood components is provided below.

2.5.1 Blood and Blood Components[11]

Blood is comprised of a liquid component (plasma) and protein substances (red blood cells, white blood cells and platelets) and it is this combination of substances that is referred to as whole blood. The role of these components includes:

- **Red Blood Cells** carry oxygen to tissues and are responsible for removal of carbon dioxide through the lungs.
- **White Blood Cells** protect the body from infection and often carry viruses and bacteria.
- **Plasma,** the liquid portion of the blood, is a protein-salt solution in which red and white blood cells and platelets are suspended. Plasma, which is 90 percent water, constitutes about 55 percent of blood volume. It contains **albumin** (the chief protein constituent), **fibrinogen** (responsible, in part, for the clotting of blood), **globulins** (including antibodies), and other clotting proteins. Plasma can be derived from whole blood collections using a centrifugation process. Or, it is possible to use a process called plasmapheresis to extract only the plasma from a donor. Plasmapheresis allows an individual donor to donate almost twice as much plasma as from a unit of whole blood. Plasma can be fractionated (separated) into specific products such as albumin, specific clotting factor concentrates and IVIG (intravenous immune globulin).
- **Platelets** provide the basis for clotting that helps control bleeding. Platelets can be extracted from plasma that is collected as part of a whole blood donation. Or it is possible to collect only platelets and return the other blood components to the donor using a process called plateletphereis or cytapheresis.

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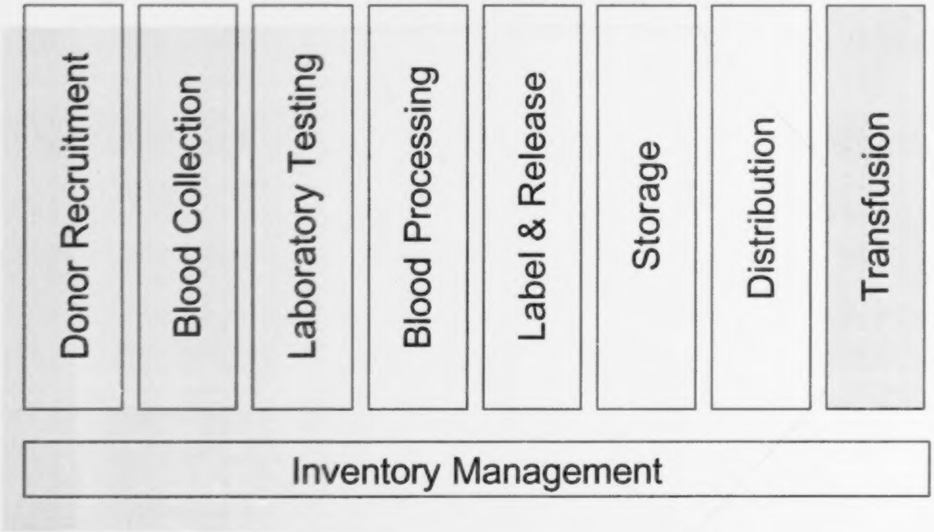
[11] This information is taken from the CBS website (www.bloodservices.ca)

2.5.2 Key Functions of the Blood System

The major components of a blood system are illustrated in the following diagram. The role of CBS extends from donor recruitment to distribution. Transfusion and therapeutic interventions involving blood components are the responsibility of hospitals within each provincial/territorial health system.

Exhibit 2-7: Components of the Blood System



2.5.2.1 Donor Recruitment

Donor recruitment activities are a critical function for CBS as all subsequent activities are contingent on maintaining a large, regular donor pool. Over the last decade, prior to the establishment of CBS, the total number of blood donations had decreased. Therefore, CBS was faced with the challenge of increasing donations while building the organization. One of their first major campaigns was the launching of aggressive recruitment programs and the introduction of changes to make donor processes more 'donor-friendly'. Public service announcements and advertising campaigns such as "Roll Up Your Sleeves Canada" are part of a multi year plan intended to recruit 160,000 new regular donors by December 31, 2005.

All donations are voluntary and donors must be between 17 and 70 years of age. Statistics collected by CBS indicate there are approximately 465,555 active donors today; yet of eligible Canadians (excluding Quebec), only 3% are regular donors. Of these donors, 85% are repeat and 15% are first-time donors.

As indicated in the following chart, there has been a 13% increase in new donors from fiscal year 2000/01 to 2001/02. The next diagram displays the percentage of eligible donors by province.

While CBS has seen an increase in donations since its inception, attracting and persuading Canadians to become regular and frequent blood donors will always be a major part of their operations.

Exhibit 2-8: New Donors

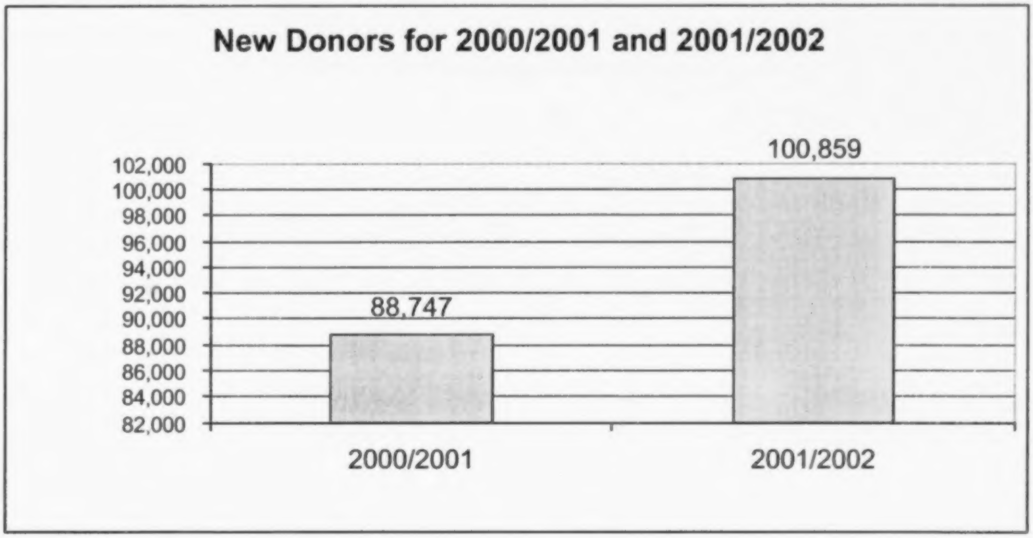
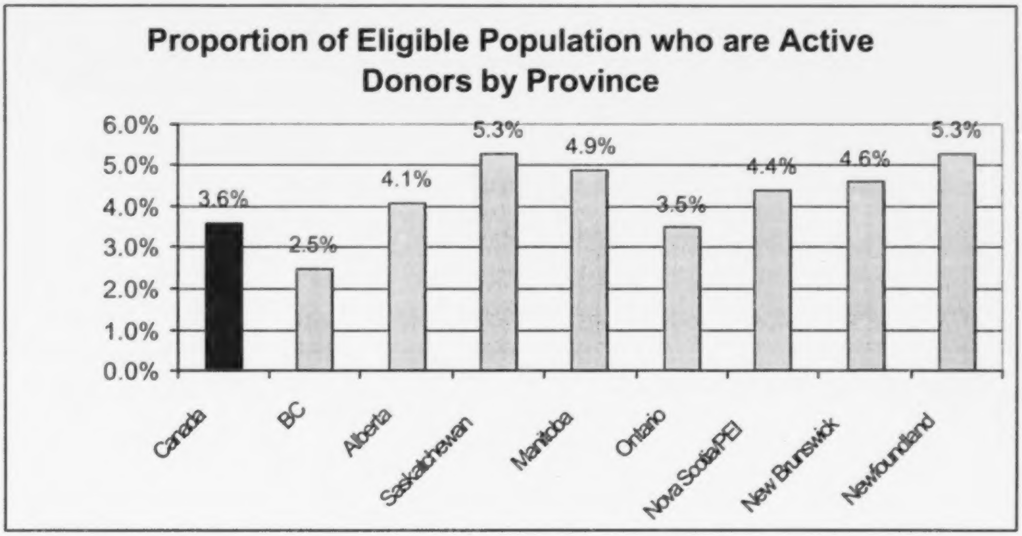


Exhibit 2-9: Proportion of Eligible Population that are Active Donors by Province



2.5.2.2 Blood Collections

Blood Collections is a core function of CBS. CBS maintains 42 permanent blood collection clinics and operates several mobile clinics each day. Mobile clinics are clinics that are held in different community locations each day. In 2001/02, CBS held 11,917 blood donor clinics, up from 11,189 for the previous year.

When a donation is made at a Centre, the donor must first answer a series of health and lifestyle related questions to determine their eligibility to donate. This extensive list of questions is to ensure the health of both the donor and ultimate recipient—a patient requiring a transfusion.

The process of blood collection requires the donor, a needle attached to a plastic tube and a sterile blood bag. The donor's blood passes through the needle and tubing into the sterile bag which is then sent to the laboratory for processing. At the same time, some blood from within the bag is taken for purposes of typing and testing for infectious agents.

The following diagram indicates an increasing trend in the number of units of whole blood collected since 1998 when CBS was established. Beginning in 1999, CBS has had to place restrictions on donations from people who have spent time in Europe because of concern about transmission of variant Creutzfeldt-Jakob Disease (vCJD). The vCJD deferral policy does not seem to have negatively impacted the volume of whole blood collections because CBS has increased efforts in the area of donor recruitment.

Exhibit 2-10: Trend in Whole Blood Collections

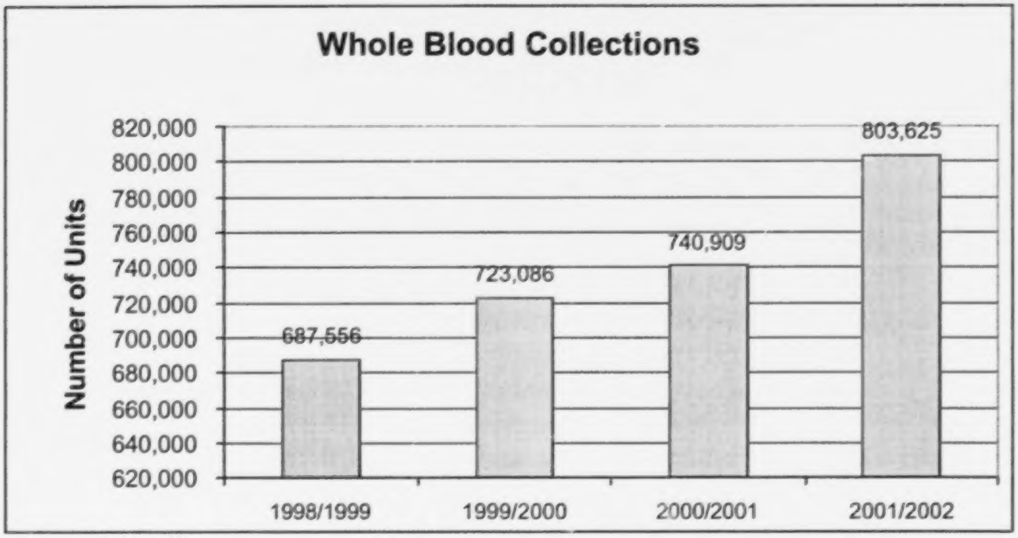
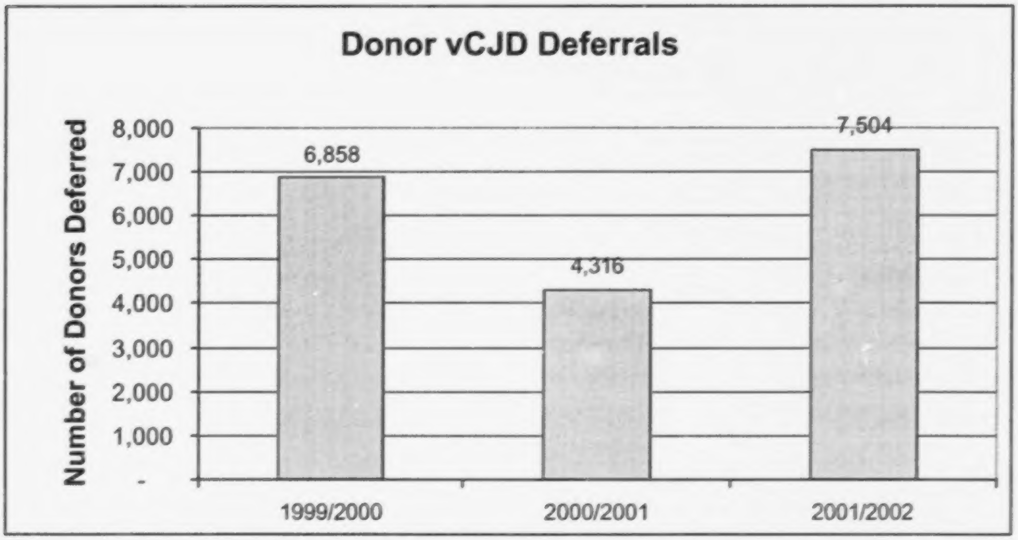
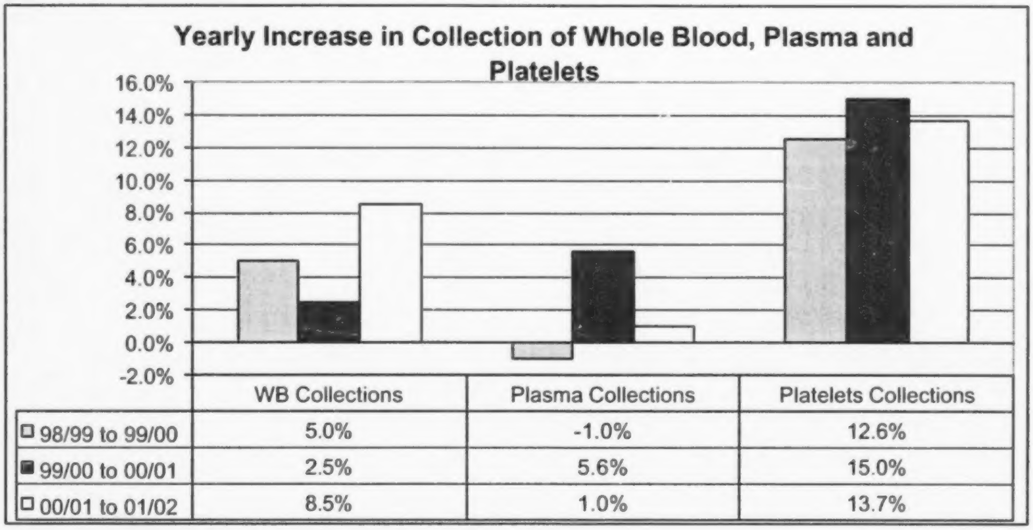


Exhibit 2-11: Trend in Donor Deferrals due to Risk of vCJD



It is from whole blood that red cells, platelets and plasma are retrieved. Red cells and platelets are generally processed and distributed directly to hospitals. Most plasma is sent to the US for processing into fractionated products. The following graph highlights the percentage increases in whole blood, plasma and platelets since the inception of CBS.

Exhibit 2-12: Trends in Collection of Blood Components



	WB Collections	Plasma Collections	Platelets Collections
□ 98/99 to 99/00	5.0%	-1.0%	12.6%
■ 99/00 to 00/01	2.5%	5.6%	15.0%
□ 00/01 to 01/02	8.5%	1.0%	13.7%

2.5.2.3 Testing

When blood is collected, samples are taken for testing purposes. Before blood is issued to hospitals for use in transfusion, the samples are tested for:

- Infectious Diseases: Syphilis, Hepatitis B and C, HIV 1 and 2 (the viruses that cause AIDS) and Human T-Cell lymphotropic virus HTLV-I and II (the viruses that can cause a rare form of leukemia in adults and chronic nervous system disease)
- Blood Groups and Antibody Screening: to determine ABO and Rh type, blood group antibodies

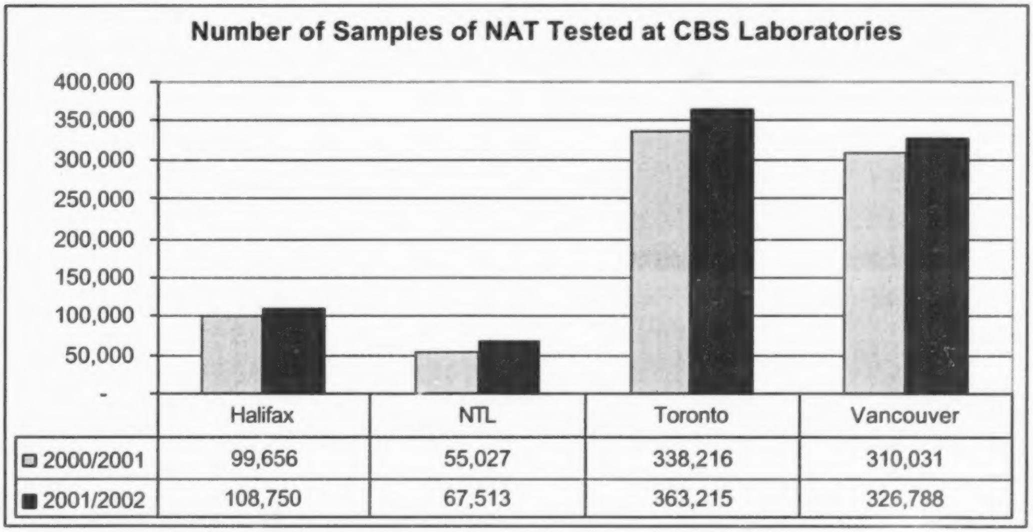
Laboratory tests for infectious diseases, blood groups and antibody screening are conducted on each unit of blood collected. If the blood or plasma tests positive for any disease marker, it is destroyed and the donor is notified of the abnormal test results. These donors are then permanently deferred and will not be permitted to donate blood in the future. Blood samples that test positive at a Centre laboratory are sent to the National Testing Laboratory (NTL) in Ottawa for confirmatory testing.

Nucleic Acid Amplification Testing (NAT) is a relatively new form of testing that is done at four CBS laboratories. CBS uses NAT for Hepatitis C and HIV testing.

The following diagram identifies the number of NAT samples tested in each NAT laboratory (Vancouver, Halifax, National lab in Ottawa, and Toronto) for fiscal years 2000/01 and 2001/02. A total of 866,266 samples were tested in 2001/02. As noted above, the National lab in Ottawa re-tests samples that were tested at the Centres as required. This explains why the total number of samples tested is greater than the units of whole blood collected – some units are tested more than once.

NAT testing is discussed further in section 5.2.1.1.

Exhibit 2-13: Number of Samples NAT Tested



	Halifax	NTL	Toronto	Vancouver
□ 2000/2001	99,656	55,027	338,216	310,031
■ 2001/2002	108,750	67,513	363,215	326,788

As part of efforts to achieve greater organizational efficiencies, CBS will be centralizing its testing at three laboratories located in Calgary, Toronto and Halifax. This is discussed in section 2.6.

2.5.2.4 Manufacturing

Once collected from a donor, each unit of whole blood is processed by a Component Production lab, assessed for suitability, and separated by centrifugation into the following components:

- Red blood cells
- Plasma
- Platelets

- Cryoprecipitate
- Cryosupernatant

Each unit of blood also undergoes 'leukoreduction" a filtration process that removes the white blood cells to reduce the incidence and severity of transfusion reactions.

2.5.2.5 Label and Release

When the testing and production are complete, the components are then sent for Label and Release. All production and testing records are reviewed for suitability, completeness and accuracy, and each component is labelled with all applicable labels. The labelling is then verified for accuracy before the blood components are released to inventory, and available for distribution to hospital customers. Units are labelled to indicate:

- Donor Identification Number (DIN)
- Blood Type
- Blood Product
- Date of collection
- Date of expiration

At this time, the expiry date process mandated by Health Canada is done manually. It is anticipated the introduction of the new MAK Progesa computer system will negate the need for this manual process.

The automation of this process will also improve the ability to track inventory. For example, the current process of determining total inventory counts requires that an individual manually count each unit of blood component. Clearly, this is a labour intensive process subject to human error as are all manual processes.

Once products are labelled, they are committed to an inventory and thus, available for release to a hospital.

2.5.2.6 Fractionation

CBS operations are divided into two streams; blood operations, which deal with fresh blood and blood components, and fractionation, whereby plasma is frozen for shipment to a fractionation centre in the US.

As the volume of Canadian plasma shipped to the US is insufficient for national needs, American plasma is also used in the fractionation process. At the fractionation centre a number of different products are produced and shipped back to CBS for distribution to

CBS Centres and then hospitals. Factor VIII, albumin and intravenous immunoglobulin (IVIG) are the most common fractionation products produced.

CBS receives fractionated products processed in two ways; 1) the Canadian plasma sent to the fractionator is used specifically for Canadian fractionation products (referred to as custom fractionation) and 2) CBS purchases fractionated product manufactured from American plasma (referred to as commercial product).

2.5.2.7 Distribution

The Centres receive orders for blood products and fractionated products from their hospital customers by fax or by phone. CBS laboratory staff monitor inventory levels of all products and fill the hospital orders as they arrive. The appropriate components are then retrieved, checked, packed, and shipped to hospitals for patient transfusion.

2.5.2.8 Transfusion

A critical event in the blood collection and manufacturing process is the transfusion to a patient. Hospitals report adverse reactions to CBS as part of their overall surveillance function. CBS in turn communicates with Health Canada regarding adverse transfusion reactions. Beyond this reporting requirement, there are no other formal mechanisms in place to enable CBS to track a unit of blood from the vein of the donor to the vein of the recipient. To date, CBS has no authority regarding how blood products are used within the boundaries of the hospital system. This is the responsibility of hospitals, clinicians and, ultimately, provincial/territorial Ministries of Health.

2.5.2.9 Inventory Management

The entire blood collection and manufacturing processes are manually intensive. This makes for an unwieldy and inefficient process; for example, inventory counts must be conducted by hand as there is no other method of keeping track of 'real time' inventory levels. MAK Progesa will automate these currently manual processes, resulting in greater process efficiencies in areas such as:

- Storage of blood donor recruitment data
- Tracking of blood components
- Labelling
- Order management
- Inventory management

2.5.3 Challenges

In spite of a trend of increasing units of whole blood collection, CBS must contend with a declining donor base. The challenge that continues to face CBS is in creating a significant public awareness campaign aimed at increasing the percentage of eligible donors who are committed to a program of regular blood donations.

Another challenge will be in balancing the adoption of emerging best practices and cost efficiency. For example, since the implementation of NAT, several countries are reconsidering the ongoing use of this test based on the number of HIV and HCV cases uncovered.

While CBS is working hard toward developing and implementing efficient work processes based on nationally derived standards, there are still many inefficient and fragmented work processes. This will require integrated information systems and a more rapid move toward standard work processes.

2.6 The Transformation Project

2.6.1 History and Rationale for the Transformation Project

When CBS took over operations from the Red Cross, they inherited a system that can be described as:

- very manual and labour intensive
- highly duplicative
- paper based and error prone
- inflexible to shifts in demand
- reaching its limit in terms of capacity expansion
- increasingly expensive.

In 1999, the new management of CBS identified strategic directions required for an integrated blood system. The first step identified in achieving this was to design and implement:

> *"an Organizational Model and Service Delivery Systems to enable CBS to achieve its vision and mission as well as to identify and implement the services and support that CBS should provide to its customers."*[12]

Various external consultant reports confirmed the need for improvement of many CBS systems.

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[12] CBS Report to Canadians 1999/2000

According to CBS, the initial design of their new organizational model and service delivery system was comprised of two phases: Phase 1 focused on obtaining information about the current organization, identifying issues and suggestions, and soliciting ideas for future direction, and Phase 2 was to establish overall directions to guide the development of the new model.

By Fall, 1999, the initiatives under consideration included:

- Development of a national donor recruitment and retention strategy to guide overall recruitment and management programs
- Redesign of clinic processes with a focus on donor needs that included consideration of issues such as clinic locations, appointment procedures, recognition programs and other opportunities to support donor convenience and enthusiasm
- Improvement of collections processes and increased focus on collections efforts in high yield areas
- Consolidation of specialized testing locations that consider cost-effectiveness, redundancy, geography and weather conditions on transportation
- Establishment of national inventory capabilities to ensure excess supply of blood and blood products are provided to areas with shortages/limited supply
- Encouragement in developing utilization management approaches through planning and education of their professional colleagues and in collaboration with Provincial and Territorial representatives
- Providing effective strategy and policy support from Head Office to local operations, the new model must incorporate a capability to locate support services in the field, where possible.

CBS reports this Organization Model / Service Delivery project was delayed in the Fall 1999 due to a number of more urgent and costly challenges:

- Health Canada had just introduced a directive for universal leukoreduction approximately one month after CBS took over the Red Cross blood operations
- There had been no consideration of, or preparation for, Y2K
- Implementation of HCV NAT was initiated
- Health Canada had introduced the first deferral policy for donors having traveled to the UK

At the same time, CBS recognized the need to structure their services and processes in the most cost effective way possible but without compromising safety. Winter 2000 saw the Organization Model / Service Delivery project re-launched as the Transformation Initiative.

Initially, there were 28 Transformation projects identified. CBS Executive Management Team (EMT) recognized the need to select the projects based on a set of prioritization criteria based on project interdependencies with other systems, potential cost savings and an understanding of what resources were available to carry out implementation. In the summer of 2001, the following projects were identified as priorities and the EMT gave instructions to proceed with the following projects:

- Implementation of the MAK Progesa system
- Creation of a National Contact Centre - Donor Contacts only
- Consolidation of Testing Centres
- Consolidation and Specialization of Production
- Implementation of a Change Control System
- UBMDR
- Implementation of SAP HR/Payroll (this project went live July 1, 2002)

These seven key projects are proceeding, but are at different stages of implementation and CBS is working to ensure that the projects are well coordinated and well aligned. A brief description of each priority project is provided below:

2.6.2 MAK Progesa

MAK Progesa is an information system linking donor recruitment, collections, blood component production, testing, labeling, hospital orders and inventory management. It will also replace the current non-integrated information systems, resulting in a truly national and integrated blood system. The MAK system will enable CBS to better track blood donations from the donor through to delivery to the hospital. At this time, the pilot site for this system is Halifax. CBS staff have been working with the Health Canada regulators for some time to ensure the right SOPs are developed, approved and ready for implementation at the 'go live' date in February, 2003. Full implementation across all Centres is anticipated for late 2003.

The specific objectives of MAK include:

- The creation of a single national database available to all CBS sites
- Enabling end-label practice to be implemented
- System component suitability and discard controls
- System reconciliation of component production
- Electronic transfer of all test results
- The ability for all components to be traced from collection to distribution
- On-line, real-time inventory of all components on a national basis
- Elimination of stand alone systems The decision to pursue MAK implementation was actually made by the Canadian Blood Agency just prior to the creation of CBS because the existing systems were not Y2K compliant. It appears that

there was no business case developed at the time. CBS is currently developing a business case for MAK.

Recommendation #12: CBS does not have a completed business case for implementation of MAK Progesa because the decision to implement MAK was made by the Canadian Blood Agency before CBS was formed in 1998. It is recommended that CBS expeditiously complete the business case for MAK that is currently under development.

2.6.3 Donor Contact Centre

February 2002 saw the public announcement of Sudbury, Ontario as the site of the new National Contact Centre, estimated to be implemented by February 2003. The purpose is to create system-wide cost-efficiencies consolidating all donor recruitment and booking functions under a single roof. The new Centre will handle functions such as:

- Booking donor appointments
- Answering questions from the public
- Recruiting donors
- Supporting marketing campaigns
- Addressing eligibility inquiries

A business case for this project was completed on November 6, 2001.

2.6.4 Consolidation of Testing Centres

This project involves a two-phased approach to consolidation of testing. Initially, testing will be consolidated from 11 laboratories to three laboratories in existing facilities (Calgary, Toronto and Halifax). The rationale for this change is to enable CBS to focus on economies of scale, standardization and automation, and to move from manual to more technological work processes. An anticipated benefit is improvements to the safety and quality of the blood system.

This consolidation of testing will be made possible with the introduction of new technology called PRISM that will both increase capacity and reduce product losses and recalls. PRISM is expected to drastically reduce the staffing required for immunoassay testing. The PRISM equipment and the reagents required for testing have been approved by the Canadian regulator. However, since CBS also sends plasma to the U.S. for fractionation there is a requirement for the PRISM reagents that will be used to test the plasma to receive approval from the American regulator as well. CBS is currently working on this approval. PRISM technology has been purchased and is in place, undergoing validation in Toronto.

In the second phase of consolidation, testing will be moved from the existing Centres to new, stand-alone, state-of-the-art testing facilities. A major reason offered by CBS for building the new testing facilities is to locate the facilities closer to transportation channels (e.g. airports) to expedite transport of samples for testing. The expert panel assembled for this review had concerns about this rationale and felt that the timing of the delivery of samples is unlikely to affect the critical path for the testing process given the length of time required for the tests to be completed (usually overnight).

While there is a document outlining the issues, risks and recommendations associated with this project, a comprehensive business plan was not available for review by the consulting team.

2.6.5 Consolidation and Specialization of Production

The purpose of this project is to streamline production functions. The current 14 production sites are all used to produce a range of blood products from whole blood. At present, each Centre also maintains an inventory of all frozen products (for example, fresh frozen plasma, cryoprecipitate, and cryosupernatent plasma)

The scope of this project is to evaluate CBS production locations and recommend a reduction in the number of locations that will be used to produce and issue frozen plasma components. The planning for Specialized Production is complete and implementation is scheduled for mid-August in London and mid-October in Regina. For Consolidated Production, the planning phase will be completed by September 2002, to be followed by implementation.

A business case was completed on February 2, 2002.

2.6.6 Implementation of a Change Control System

The Change Control System refers to the establishment of a policy that will assure all changes will be controlled by evaluating, approving and monitoring all changes that may impact CBS operations. The purpose is to ensure all changes are properly documented, evaluated and authorized by qualified personnel. Work is underway to design four critical elements:

- Document Management
- Validation
- Non-conformance System
- Training

These elements are anticipated to be presented to Health Canada by the end of September 2002. A business case for an automated solution was presented to the Executive Management Team in mid-August 2002.

2.6.7 Unrelated Bone Marrow Donor Registry

Due to scientific advances and improvements to information technologies, a plan (initially begun in 1988) was developed for the enhancement of the UBMDR information system. The objectives of this new registry are to enable:

- Integration of existing processes into a single centralized system
- Integration of HLA typing
- Automation of preliminary search requests
- Provision of rapid search results
- On-line search status
- Focused recruitment campaigns
- Attaining International accreditation

A business case was completed in November 27, 2001. This system was implemented on June 24, 2002.

2.6.8 Implementation of SAP HR/Pay

Until this project was implemented, each Centre was responsible for their own HR / Payroll functions. While staff are still adjusting to changes brought about by implementing a standard, national pay system, the specific benefits were identified as part of the 'go forward' decision:

- More consistent and efficient human resources, time and payroll processes across the country
- Enhanced ability to manage human resources more effectively
- Improved controls and accuracy of human resouces, time and payroll functions

The first payroll was prepared by the new system in June 2002.

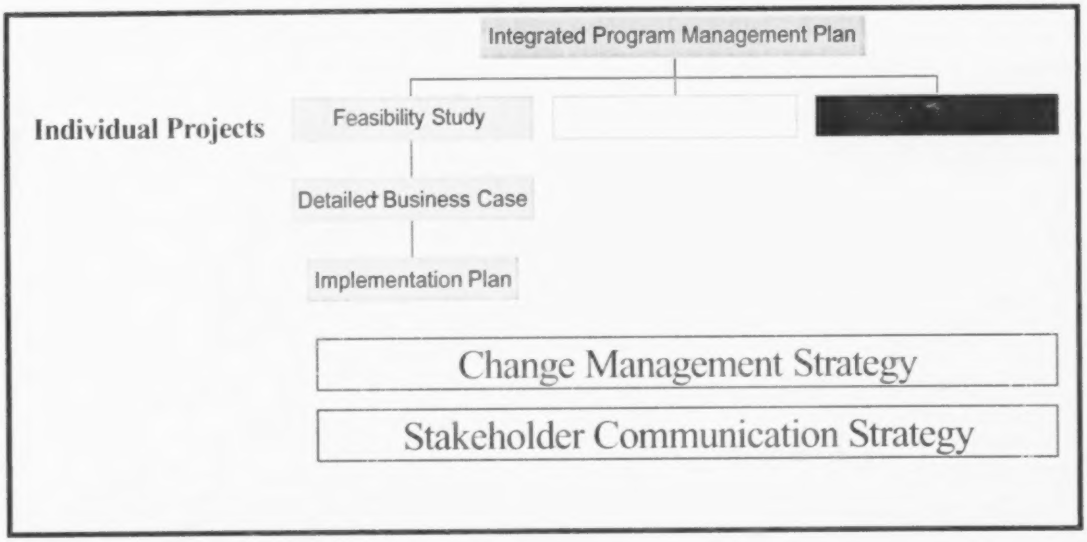
2.6.9 Challenges

The Transformation Initiative is a major undertaking that will substantially change the operations of the organization. However, a number of stakeholder groups raised some common concerns that must be addressed. These concerns include the timing, quality and regularity of communications to impacted staff and stakeholders. CBS Centre staff are too often unaware of what, when and how Transformation will affect them and this hampers their ability to alleviate concerns or answer questions. Hospital representatives report frustration on two fronts; inadequate notice of CBS changes that impact hospital processes and the inability of CBS to meet timelines they set. For example, the implementation of MAK will have resource implicatgions for hospitals. This makes effective communications with this stakeholder group a necessity. While some staff at CBS Head Office see this as a responsibility of the regional Centres, the Centres do not feel they are sufficiently aware of the status and impact of Transformation to initiate communications with their hospital stakeholders.

Another major challenge is in understanding what projects have been selected and what is their current progress status. There are many Transformation Initiative documents available but they do not always use the same project name. While discussions with CBS staff indicate a structured approach to the Transformation projects, communications and available documentation appear less so. This observation is consistent with feedback from both Centre staff and P/T Contact staff. In order to ensure a common understanding of decisions made regarding specific projects and timelines for implementation, a more comprehensive and systematic communication strategy is required.

Recommendation #13: It is recommended that CBS develop a Transformation Communication Strategy for Corporate Members and CBS staff/volunteers that uses consistent language and provides for regular updates on project status. This could be part of the Stakeholder Communications Plan referenced earlier. As part of the strategy, CBS would clarify and communicate to the Corporate Members and the P/T Contacts at the earliest opportunity, how each of the Transformation initiatives that is being planned will be financed. This must include a description of operational and capital cost requirements and the projected timing of both funding investments and cost savings.

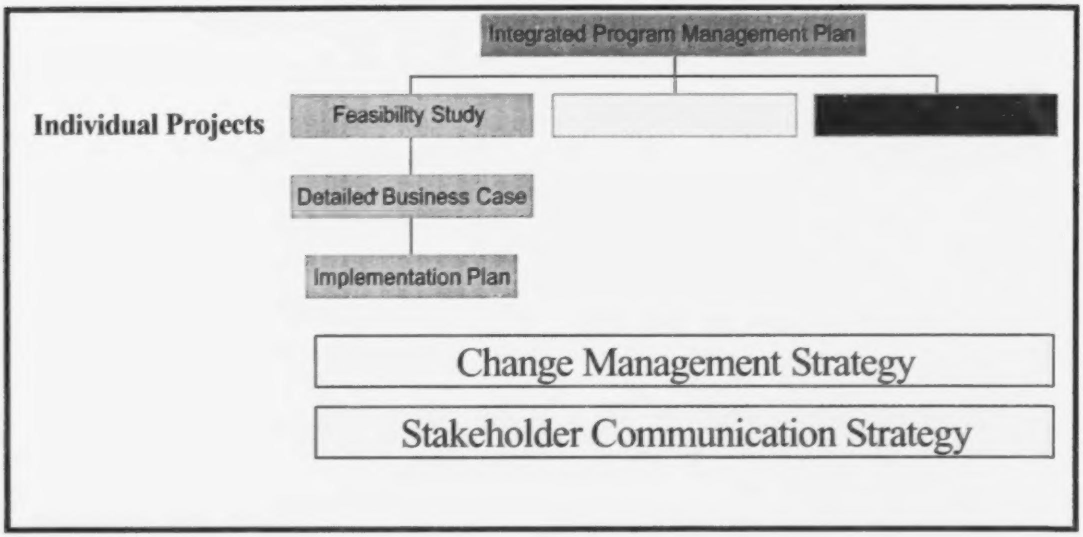
Recommendation #14: The planning phase for Transformation has been long and many of the projects identified are intended to be organization-wide. Managing the complexity and project interdependencies of any national, large-scale initiative is a challenge. It is recommended that CBS implement a rigorous program management methodology for Transformation as soon as possible. The program management methodology should include development of an integrated project plan that shows how all of the projects fit together, costs, benefits, phasing and interdependencies.(see below)


Integrated Program Management Plan
Individual Projects
Feasibility Study
Detailed Business Case
Implementation Plan
Change Management Strategy
Stakeholder Communication Strategy

Recommendation #15: CBS has undergone, and continues to undergo, a great deal of change in many areas. Staff are change weary and they will require a great deal of support, training, information and communication to make the Transformation Project a success. It is recommended that CBS implement an organization-wide Change Management strategy for the Transformation Initiative as soon as possible. Ideally, a dedicated staff position should be identified to lead the Change Management program. [It was noted that during this review, recruitment was underway for a Manager of Organizational Development at Head Office whose role will include Change Management, among other duties.]

Recommendation #16: While CBS has provided business cases for some of the Transformation Initiatives, it is recommended that business cases be developed in a timely manner for all projects that are being pursued. Each business case should include at least the following information:

- Full description of the initiative
- Timeframes for planning, implementation and evaluation
- Description of costing methodology and planning process
- Application of the cost, benefit, risk framework mentioned in the MOU
- All costs (planning, implementation, ongoing, capital)
- Timing of cost outlays and cost savings
- Expected benefits and how they are to be achieved and measured (e.g. cost savings, safety impact, supply impact, efficiency gains, automation improvements, staffing impact, donor impact)
- Performance measures and targets
- Implications/risks (e.g. product supply impact, staffing impact, donor impact, regulatory impact)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- Expected benefits and how they are to be achieved and measured (e.g. cost savings, safety impact, supply impact, efficiency gains, automation improvements, staffing impact, donor impact)
- Performance measures and targets
- Implications/risks (e.g. product supply impact, staffing impact, donor impact, regulatory impact)

- Financial and operational performance metrics to be used for the initiative

Information should also be provided on the impact in the province of each member.

2.7 Regulatory Framework

Throughout the 1980s, the federal department with regulatory responsibility over food, drugs and the environment was the Health Protection Branch (HPB). The approach taken toward enforcement of regulations though, was one of "voluntary compliance". Krever quotes the then HPB Assistant Deputy Minister:

> *"the branch promoted voluntary compliance throughout the 1980s. The flexibility it allowed was preferable to issuing regulations and learning that they were not necessary or had become outdated and then having to remove them. Voluntary compliance is a much more appropriate and efficient and effective way of doing it [regulating]. And by and large, I have to say that voluntary compliance permitted us to extend the purview, to extend the examination of a wider range of areas than would otherwise be possible because regulation and regulatory action is very expensive ..."*

This statement reflects the history but, a different philosophy exists today.

2.7.1 Current Role of Health Canada

Today, the federal government, through Health Canada's Blood Establishment Regulatory Division, is responsible for regulating the blood system. Health Canada's regulatory framework is the laws, policies, standards, directives, guidelines and regulations outlining the legal requirements from collection to the distribution of blood and blood components.

Since 1988, blood and blood products have been regarded and regulated as drugs. The *Food and Drug Regulations* established the means by which the Minister of Health (Canada) might be satisfied that the premises, processes and conditions of manufacture "are suitable to ensure that the drug will not be unsafe for use." Specifically, it is *Divisions 1A* (i.e. Establishment Licences), *2* (i.e. Good Manufacturing Practices) and *4* (i.e. Schedule D Drugs) of the *Food and Drug Regulations* that are the regulations applicable to blood and blood components.

Since Krever, Health Canada has strengthened its regulatory role in relation to the blood system; they have increased their inspection activities, issued guidelines based on current Good Manufacturing Practices, approved each Standard Operating Procedure and issued an annual license to both of Canada's blood systems. Health Canada sets out the minimum requirements for acceptable performance as it relates to donor selection, blood collection, blood processing, testing, labeling, record keeping, lookback / traceback, recall and storage.

As part of the enhanced role of Health Canada, an Expert Advisory Committee (EAC) on Blood Regulation was appointed in 1995. Members of this committee include representatives from the medical and scientific communities as well as from within Health Canada. Their role is to provide timely advice on emerging issues and federal responsibilities within the blood system. In 1997, the Minister of Health Canada also appointed a National Blood Safety Council to provide advice on issues related to public health, ethics, and public policy related to the blood system.

Ultimately, the current role of Health Canada is to reduce the risk of transmission of a disease through blood components or products by ensuring there are procedures established and followed that will preclude or at least minimize the probability or extent of contamination of any pooled biological material.

2.7.2 Good Manufacturing Practices

Blood is defined as a bio-pharmaceutical product and must be manufactured following strict regulatory standards. The Good Manufacturing Practices (GMP) standards refer to Division 2, Part C of the *Food and Drug Regulations* and are the minimum legal requirement applicable to all regulated industries to ensure consistency when applying Health Canada's regulatory requirements to their work processes. Associated with these legal requirements are associated 'guidelines' aimed at helping CBS and Hema-Quebec implement relevant GMP standards. These however, are not the only standards to which CBS can be held. For example, as the two plasma centres provide a biological product for shipping and processing in the US, they are also subject to all relevant US Food and Drug Administration regulations.

CBS and Health Canada independently track and monitor current and emerging international standards in blood safety through mechanisms such as participation in international advisory committees, the creation of safety advisory committees and / or by benchmarking practices against other blood agencies. For example, in November 1998, Health Canada issued a directive to CBS calling for implementation of pre-storage leukoreduction of red blood cells and platelets. On the other hand, CBS took the initiative to implement Nucleic Acid Amplification Testing (NAT) without being directed to do so by the regulator. However, the regulator did make NAT testing a condition of license for CBS. Therefore, while not a 'directive' per se, as in the case of leukoreduction, "condition to license" means that the license (to operate the blood program) is in effect so long as CBS addresses NAT testing. These measures were based on evolving international standards aimed at proactively improving the safety of the blood system.

Health Canada does not regard the GMP standards as the only interpretation of the GMP regulations, nor were they intended to cover every conceivable case. For example, alternative means of complying with these regulations can be considered with the appropriate scientific justification and different approaches may be called for as new technologies emerge.

The guidance given in the Good Manufacturing Practices Guidelines has been written with a view to harmonization with GMP standards from other countries and those of the World Health Organization (WHO), the Pharmaceutical Inspection Cooperation/Scheme (PIC/S) and the International Conference on Harmonization (ICH).[13]

The GMP standards therefore, are a 'living' set of standards intended to be flexible enough to apply as new medical and scientific information emerges[14]. The application and regulation of GMP standards however, have a direct and ongoing impact on the operations of the CBS.

2.7.3 Organizational Impact

CBS must ensure that the manufacturing, packaging, labelling, distribution, testing and delivery of blood components complies with GMP requirements. The responsibility rests with the senior management (and ultimately the Board) and requires the participation and commitment by personnel in many different departments and at all levels within CBS and by its suppliers.

Good Manufacturing Practice standards are concerned with both production and quality control and Health Canada describes their basic requirements[15]:

- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications
- Manufacturing processes are controlled and any changes to the process are evaluated

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[13] Health Products and Food Branch Inspectorate, *GOOD MANUFACTURING PRACTICES GUIDELINES* 2002 EDITION. Supersedes: 1998 Edition. Date issued: 2001-12-01. Date of implementation: 2002-01-01.

[14] http://www.hc-sc.gc.ca/hpfb-dgpsa/bgtd-dpbtg

[15] Health Products and Food Branch Inspectorate, *GOOD MANUFACTURING PRACTICES GUIDELINES* 2002 EDITION. Supersedes: 1998 Edition. Date issued: 2001-12-01. Date of implementation: 2002-01-01.

- Changes that have an impact on the quality of the drug are validated as necessary
- All necessary key elements for GMP are provided including:
    - qualified and trained personnel
    - adequate premises and space
    - suitable equipment and services
    - correct materials, containers and labels
    - approved procedures and instructions
    - suitable storage and transport.
- Instructions and procedures are written in clear and unambiguous language
- Operators are trained to carry out and document procedures
- Records are made, manually or by instruments, during manufacture which demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the drug was as expected. Deviations are investigated and documented
- Records of manufacture including distribution which enable the complete history of a batch to be traced are retained in a comprehensible and accessible form
- The distribution of the drugs minimizes any risk to their quality
- A system is available to recall any batch of drug, from sale or supply
- Complaints about marketed drugs are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective drugs and to prevent re-occurrence

How CBS translates these requirements into work processes for the organization is through the development of Standard Operating Procedures (SOPs). These documents must be approved by Health Canada before implementation and become the processes all staff must follow from donor recruitment through to the delivery of product to hospitals.

2.7.4 Compliance Performance of the CBS

CBS has worked hard at introducing the structures and processes required for working in a regulated environment. This is not always easy; staff do not always understand the rationale for the lack of professional autonomy a regulated work environment requires and staff are not always comfortable with their work being scrutinized rigorously by internal or Health Canada auditors.

At any time throughout the year, there is an audit underway in at least one Centre or at Head Office. It is important to remember to understand the challenges faced by CBS as they implement a manufacturing model into an organization that is manually driven and therefore prone to errors. In spite of this, staff express a strong commitment to continual process improvement.

Health Canada states[16] that over the last five years, they and CBS have worked to improve and maintain the level of confidence in the blood system. The overall compliance performance of CBS was described as "good". The one area they identify needing improvement is in a consistently timely response to citations. The anticipated changes to Health Canada's regulatory framework may also help provide CBS with clearer guidance with respect to regulatory requirements.

2.7.5 Controlled Documents and Standardization

A Standard Operating Procedure is a type of controlled document used for the procurement of materials, donor management and services, the processing, testing, disposition, release, distribution and outcomes reporting of blood products; or a procedure that is used by the supporting functions of CBS, not directly involved in the activities as defined above, (e.g., Payroll). SOPs precisely describe the tasks / activities required for work process and staff must adhere to the steps within the SOP; there is no leeway for individual interpretation of an SOP. For example, a phlebotomy performed in Vancouver must be performed precisely the same way and with the same equipment in Halifax. Failure to do so will result in a citation by the Health Canada or CBS Quality Systems audit staff. This precision in work processes can make it very challenging for staff unused to working in a regulated environment.

Because each SOP is a controlled document, each one must be assigned a unique identifier used to control, monitor and retrieve it. The administrative tasks and time required to maintain SOPs and other controlled documents is significant. The following table identifies the number and type of SOPs that have been identified by CBS. There are a total of 961 SOPs and CBS reports that 300 to 400 of them have been implemented.

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[16] Interview questionnaire responses from Ms. J. Hill, Acting Director General, Biologics & Genetic Therapies Directorate, Health Canada. July 2002.

Exhibit 2-14: Standard Operating Procedures by Functional Category

CANADIAN BLOOD SERVICES
STANDARD OPERATING PROCEDURES (SOPs) as of March 2002
Source: SOP Business Process Flow Map, Version 15.0, 2002-03-04, CBS

Functional Category	Number of SOPs
Collections	88
Component Production	60
Testing	160
Labelling/Release of Finished Components	14
Product Management	40
Head Office Manufacturing	15
Information Management	72
Quality Assurance	103
Quality Management System	28
Administrative Systems	1
Research and Development	2
Plasma	26
Equipment Operation	105
Equipment Maintenance	99
Equipment Calibration	28
Equipment Verification	64
Reagents and Supplies - Preparation and Quality Control	53
Reagents and Supplies - Instructions for Use	3
Total	**961**

At CBS, controlled documents include not only Standard Operating Procedures (SOPs), but also:

- Centre Operating Procedures (COPs) are written descriptions of Centre processes that define how to perform general tasks in place at the Centres. These are based on the SOPs but are tailored to meet the unique requirements of any of the 14 Centre sites
- Departmental Operating Procedures (DOPs) define the administrative management processes in place in the individual departments
- Centre Supplements are procedures that outline the specific information in an SOP permitted customization to address the differences for the following:
    - To document a site's choice between several approved procedural options
    - To adapt the SOP to constraints imposed by locally acknowledged authorities, as specified in the Operating Procedure

- Directives are a CBS Executive Management sanctioned, controlled document, used to convey an immediate notification of a new requirement or change to an operational process or procedure that is required to be implemented without delay. The Directive will be in effect only as long as is necessary to process the emergent change to the affected documentation describing the operational process.
- Information Bulletins are a CBS Executive Management sanctioned, controlled document, used to convey an immediate notification of a new requirement or change to general information, not directly related to operational procedures or processes. An example would be a supplier name or address change. These bulletins are in effect until such time as any documentation referencing the changed information has been updated through either a need for a procedural revision or the periodic review process.
- Manuals are large operational procedures or reference documents that may be divided into discrete instructional sections, or may be issued in their entirety. If divided, the individual sections will be revised, approved, distributed and controlled as separate entities.
- Forms are a paper or computer controlled document with blank areas for recording and organizing specific information items in a standardized manner.
- Labels are a form used for identification purposes, usually on materials or products.
- Training Documents are materials designed to aid in the training of CBS employees in the SOPs required to fulfill their assigned job functions, and
- Job Aids are an approved, controlled document that contains a section of information that has been extracted directly from an approved Operating Procedure, maintaining the integrity of the original wording. This document maintains a reference to both the document number and revision number of the source Operating Procedure.

2.7.6 Cost Drivers and Regulatory Pressures

To date, CBS reports there are approximately 29,000 controlled documents and each controlled document must be logged, maintained and tracked within the organization. There are three factors that increase the complexity in making changes to controlled documents: 1) the time required by CBS to write new or amended SOPs, 2) the number of manual processes required to manufacture blood and blood components and 3) the time it takes Health Canada to approve changes to SOPs.

Every manufacturing process requires an SOP and CBS staff report it can take up to 18 months from the time a SOP is written and approved by Health Canada. For every new or amended SOP, there is also the corresponding need to have written and approved training procedures outlining how CBS will ensure staff are trained to the new or amended SOP. This process is clearly burdensome, requiring significant investments of staff and management time.

The impact of inheriting a system where regional Centres functioned as separate entities can be seen in the duplicative and labour intensive processes of implementing national SOPs. SOPs are created by the Head Office to implement Health Canada regulations across all sites. SOPs tend to be very specific in how tasks are to be carried out, yet the Centre might be unable to implement them as written. This drives the need for developing Centre Operating Procedures.

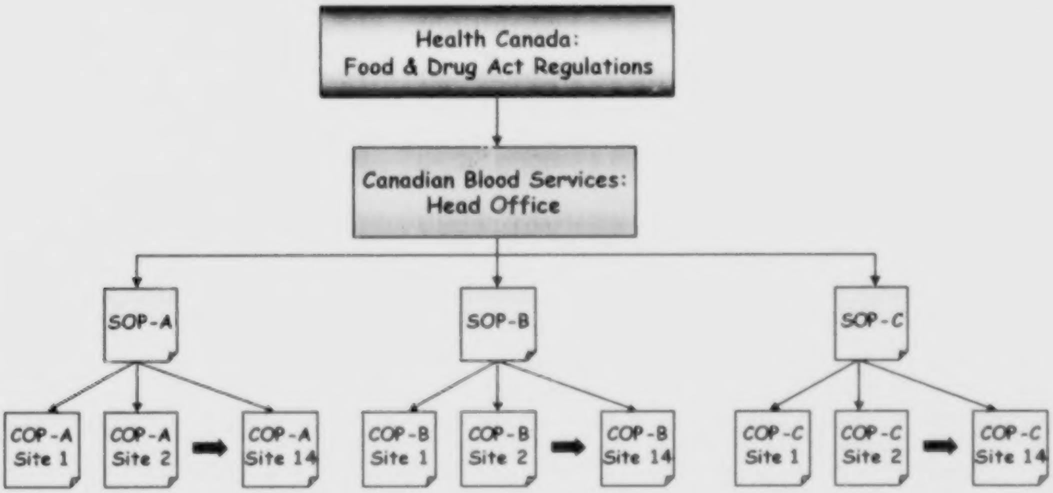
COPs are developed in order to accommodate local differences. For example, the physical layout in a Centre, equipment, facilities or local union agreements may make a SOP from Head Office impossible to implement at the Centre level. In other situations, a COP may be the outcome or corrective action of audit observations specific to the Centre (both internal, corporate and Health Canada).

The creation of a COP however, is not an arbitrary event; there are broad guidelines set out in an SOP, (SOP CQ/1000 version 1, section 4) on when a COP can/should be considered:

"the decision to undertake development of a new Procedure or revision of an existing Procedure shall be the responsibility of.....the Quality Assurance Specialist for COPs..... The Quality Assurance Specialist shall be responsible for coordinating the development and revision of Centre COPs. Centre COPs shall be prepared to provide Centre staff with detailed instructions necessary to implement National SOPs. Note: Centre COPs cannot redefine limits or standards set in National Standards or National SOPs.

The challenge to CBS however, is in the sheer number of COPs that are currently in existence. To illustrate, the following diagram demonstrates how a single SOP can be turned into a different COP for each Centre.

Exhibit 2-15: Proliferation of Centre Operating Procedures


Health Canada:
Food & Drug Act Regulations
Canadian Blood Services:
Head Office
SOP-A
SOP-B
SOP-C
COP-A Site 1
COP-A Site 2
COP-A Site 14
COP-B Site 1
COP-B Site 2
COP-B Site 14
COP-C Site 1
COP-C Site 2
COP-C Site 14

This potentially duplicative, unwieldy and manual process is a significant Process Control and administrative challenge that requires considerable time and energy to manage. CBS is well aware of the need to stream line this process. Given the current Regulatory-SOP process, their success in reworking this process will be somewhat hampered given the different physical layout and equipment in each of their Centres.

In spite of this challenge however, there is opportunity to standardize processes to reduce staff frustrations and minimize the volume of rework needed to perform common tasks. It is also anticipated that the integrated MAK system will reduce the unnecessary variation that exists across Centres and contributes to COP development. Another opportunity that was identified by Centre staff is to allow for more input from a broad range of Centres when SOPs are being developed so that local differences can be recognized upfront.

Recommendation #17: Although there has been improvement in the establishment of a national model, there is still significant variation across the regional Centres. This variation exists in the scope of services, operating procedures and the nature of equipment and facilities. It is recommended that CBS continue its efforts to increase the level of standardization in the Regional Centres. This should include:

- Reducing and standardizing patient services
- Developing and enforcing more rigid criteria under which Centre Operating Procedures should be developed
- Developing a standard template for demand forecasting for use by the regional

Centres

- Continuing to maximize consolidation opportunities over the long-term based on evidence-based assessments of costs, benefits and risks. A number of consolidation initiatives have been implemented or are planned; continued evaluation of the benefits and savings from these initiatives will help to identify additional opportunities (e.g. further reduction in consolidation sites or additional functions to consolidate).

Recommendation #18: According to CBS, many Centre Operating Procedures exist because of a lack of standardization of equipment and facilities. It is recommended that CBS develop a capital plan that includes a long-range strategy to standardize equipment and facilities as much as possible within capital cost constraints that may be imposed by the funders/Members.

2.7.7 Regulatory Approval Process: Anticipated Changes

Health Canada is currently conducting a review of regulatory requirements that include issues related to the efficiency, speed and adequacy of the current regulatory framework. The purpose of this review is to continue to ensure the regulatory process is sufficient to ensure the safety of the blood system without placing an undue burden on either the regulator or CBS. It is anticipated this review will also identify gaps in guidance documents which may help provide clearer instruction for regulators and CBS with respect to Health Canada's requirements.

Health Canada states the current *Food and Drug Regulations* are difficult to follow, and do not contain provisions specific to blood collection and components manufacturing[17]. The new regulations Health Canada will be proposing will stipulate requirements that must be met with respect to safety, efficacy and quality as well as surveillance, adverse event reporting and a compliance and enforcement strategy. The areas of potential impact include:

- Management responsibility
- Quality systems
- SOPs
- Document control
- Validation and
- Training.

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[17] Health Canada website:

These new regulations will apply to establishments involved in the collection, processing, packaging, labelling, storage, importation or distribution of blood or blood components intended for transfusion. While anticipated to be several years before completion, Health Canada, in conjunction with their Expert Panel Working Group and representatives of CBS and Hema-Quebec, is working on developing National Blood Standards.[18]

Recommendation #19: Health Canada is presently reviewing and revising its regulatory framework. In situations where a new regulatory requirement is in the works that will have major cost implications, CBS should routinely prepare a detailed briefing note for Members on the process, anticipated changes to the framework, the expected impact on CBS and any action that needs to be taken by CBS or the Members.

Recommendation #20: It is recommended that the Members convene a meeting with Health Canada for a presentation on the regulatory framework and discussion of how to minimize the burden of the regulatory process for CBS while respecting safety considerations.

2.7.8 Challenges

Annex A of the MOU provides that the national blood authority will provide "standard, policy and guideline setting supplementary to any regulatory standards of federal, provincial or territorial governments;" Annex B further provides that "the Board is responsible for the development and implementation of NBA standards supplementary to any regulatory standards of the federal, provincial or territorial governments." Pursuant to these mandates, CBS maintains two separate types of procedure guidance documents or operating standards: Standard Operating Procedures (SOPs) and Centre Operating Procedures (COPs). As mentioned above, SOPs are said to number 961, of which about 300 to 400 have been implemented and guide current practice. Although an exact number of COPs systemwide is not available, it is believed to be in the many thousands. Whereas the former provide general guidance and are promulgated and approved by CBS, the latter are developed by the Centres to provide operational guidance at the bench level. They require no approval by Head Office.

The enabling documents cited do not specify which, if any, standards are to be applied to operations of CBS, although international best practices are expected by some. The review group could not identify which standards are applied operationally by CBS to the various SOPs and COPs, although several are in widespread use internationally (e.g. ISO 9000, AABB standards, UK standards). The option to introduce some standards has, in some cases, been pre-empted by law, the implementation of universal leukoreduction, for example. This should not prevent the adoption of additional standards.

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[18] "Towards Renewed Regulatory Frameworks for Blood and Blood Components intended for Transfusion and Cells, Tissues and Organs Intended for Transplantation", Health Canada

Recommendation #21: In order to further improve uniform best practices and predictability among Canada's blood Centres, a national set of standards applied to all blood facilities would be desirable. They would be divided into two categories: 1) Laws defining required practices for regulated products and processes; and 2) Standards defining ideal or precatory best practices for products and processes not mandated by law. It is within the second of these categories that CBS should be proactive. Ideal and uniform standards should be implemented nation-wide and a voluntary inspection system established to assure uniform compliance. Such standards should be referenced regarding controlling authority.

2.8 *Stakeholder Relationships*

In carrying out its operations, CBS interacts with a variety of stakeholder groups. Effective stakeholder relationships are a critical success factor in high-performing organizations. This section describes CBS' key stakeholder relationships.

Consumer Groups
Consumer groups include a variety of groups that represent blood donors, blood recipients, CBS volunteers, victims of tainted blood, and health care professionals.

Transparency is a key principle of CBS and there are many efforts made to keep these groups informed of direction and functioning of CBS. Some of CBS' efforts at acknowledging the value of the input and support of these groups include:
- Federal audit results are posted to their web site
- Board minutes are posted to CBS' web site
- Two Board meetings per year are open to the public and held in a variety of cities
- Hosting donor recognition programs
- Staff training sessions in Customer Training are being conducted for CBS staff

The National Liaison Committee

Another important way that CBS links with consumer groups is through its National Liaison Committee. This Committee of the CBS Board represents a variety of stakeholder groups that include:

- Anemia Institute
- Arthritis Society of Canada
- Canadian Association of Transplantation
- Canadian Blood and Bone Marrow Transplant Group
- Canadian Cancer Group
- Canadian Healthcare Association
- Canadian Hemophilia Society
- Canadian Immunodeficiency Patient Organization
- Thalassemia Foundation of Canada
- Canadian Society for Transfusion Medicine
- Neutropenia Support Association

The National Liaison Committee is an opportunity for these diverse groups to have input into CBS Board meetings and have replaced the original Consumer Advisory Committee.

Hospitals

Hospitals are CBS' customers. In 2001/02, CBS shipped blood products to over 500 hospitals.

Regional Centres report more focused and frequent contacts with their hospital customers and are asking for their input and collaboration on joint issues. At some Centres, staff are providing education sessions for hospital laboratory staff, which are reported as well received, especially by smaller organizations. CBS staff do report that communications with larger hospitals can be strained and still require some work. The Vancouver and Edmonton Centres have implemented a Customer Feedback Process as a mechanism for receiving regular feedback from the hospitals.

The major issue reported by hospital representatives that were interviewed is the lack of timely information from CBS Head Office (they clearly distinguish between a Centre and Head Office) regarding changes such as the implementation of the MAK Progesa computer system. The most common complaint is too little lead time as this type of project has a significant impact on hospitals. In addition to the short lead time, concern was expressed in not knowing when MAK would be implemented nationally.

The hospital survey also revealed a number of other issues regarding the level of customer service to hospitals. Detailed survey results are included in **Appendix E** and in section 5.3.

Medical Community

The National Technical Working Group on Utilization Management was recently established to serve as a medical and technical working group on blood utilization management issues and supports the Policy Advisory Committee of the Blood and Blood Products Utilization Management Initiative. This working group also provides professional leadership in assisting in identifying, designing, and implementing cost-effective blood utilization management initiatives for the optimization of patient care.

The initial Chair of the Technical Working Group shall be an individual as determined by the Minister of Health of the Province of British Columbia acting as the lead Minister for the blood system. The Technical Working Group shall be made up of the following members:

- Medical and technical experts jointly appointed by the P/T Ministries of Health and CBS. Effort shall be taken to obtain expert representation from across Canada in accordance with the structure set out in the by-laws of CBS. This would include two representatives from the following four areas of the country: (i) Atlantic, (ii) Ontario, (iii) Alberta, Saskatchewan, Manitoba, Northwest Territories and Nunavut, and (iv) British Columbia and Yukon.
- Three representatives from CBS with one such representative focussing on the operational aspects of matters being discussed.
- The Chair of the Policy Advisory Committee.

The members meet formally on a quarterly basis but meetings may be held more often as required.

Of the members interviewed for this review, there was consistency in responses to the questions related to "what areas CBS exceeded and did not exceed expectations". With regard to areas where expectations were not met, the comments related to:

- Communications (for example, there is no systematic communication mechanism with the provinces regarding changes planned by CBS);
- The perception there is an inconsistent application of Lookback / Traceback processes nationally;
- Lack of timely dissemination of results arising out of the Utilization Management Consensus Conference

Regarding areas of satisfaction, respondents indicated that CBS is generally able to supply blood products and that they meet international safety standards (e.g., leukoreduction).

One area most respondents would like to see a greater CBS presence in is physician education. This is consistent with results gathered through the hospital survey.

Recommendation #22: The MOU states that education/information programs for medical professionals is a key function of CBS. The hospital survey found that hospitals value the educational initiatives provided by CBS. It is recommended that the

CBS develop strategies to enhance its role in educating stakeholders, particularly hospitals and physicians, on blood use and transfusion medicine. These strategies should include consideration of:

- Establishment of a portal or a designated portion of the CBS website for health care professionals
- Development of standard hospital and stakeholder educational packages for use by Centres; these packages would be prepared on a regular basis such as quarterly or semi-annually
- Requiring Centres to host a minimum number of educational sessions per yearDeveloping performance measures related to education such as the number of educational sessions, the number of participants or organizations represented at educational sessions, evaluation results from educational sessions.Some provinces (e.g. Ontario) have a number of educational initiatives in place in relation to the blood system and transfusion medicine. In addressing this recommendation, CBS should work with these provinces to minimize duplication of activity.

National Blood Safety Council

The National Blood Safety Council is directly accountable to the federal Minister of Health. The Council was formed in 1997.

The purpose of the Council is to provide advice to the Minister of Health on public health, ethical, public policy, and other issues pertaining to blood safety within the responsibility of the federal government, particularly issues pertaining to blood regulation and surveillance. The Council will:

- Be vigilant over the blood system with a particular emphasis on the surveillance and regulation of blood safety. This will involve:
    - Reviewing and commenting on structure, organizational issues and relationships within the blood system and, when it is likely to affect safety of blood, the interrelations between the blood system and the broader health system.
    - Reviewing and commenting on the performance of the organizations and bodies within the blood system, with a focus on those departments in Health Canada that deal with regulation and surveillance of blood and blood products
    - Identifying any issues that may pose a risk to blood safety including emerging pathogens, chemical or physical properties of blood and failures, flaws or gaps in the risk management strategies throughout the process of recruiting donors to administration of blood and blood products, and monitoring for adverse reactions.

- Provide a forum for communication among all the stakeholders involved in the blood system, the users and public on issues pertaining to blood safety.

It is important to emphasize that the role of the Council is to be vigilant over the entire blood system, not just CBS. The span of vigilance includes Hema-Quebec, hospitals, the regulator (Health Canada) and other sectors.

The Council consists of a Chair and up to 20 members with a wide range of knowledge/skills.

Some of the issues that the Council has addressed over the years include:

- Implementation of Krever recommendations
- Solvent detergent plasma
- Nucleic Acid Amplification Testing (NAT)
- Variant CJD
- IVIG shortages
- Hospital issues
- Emergency preparedness

Current priority issues for the Council include new and emerging pathogens, inter-organizational gaps, donors, cost-containment and adequacy of supply.

Council representatives interviewed feel that progress has been made in addressing the issues it has examined because when the Council announces a forum the organizations involved start getting prepared.

There have been times over the past four years when the relationship between CBS and the NBSC was strained. The current relationship appears to be much improved. CBS is not mandated to provide information to the NBSC. However, when invited, CBS and Hema-Quebec will present information to the Council. This generally happens about twice per year. CBS also participates in forums organized by the NBSC. Recently, CBS requested a meeting with the Council to share information on the Transformation Project.

3. Financial Review

A key component of this performance review was an analysis of CBS financial performance in relation to the services provided. Balancing the need to invest in and re-build the national blood system in an era of fiscal constraint has been a challenge for the provincial/territorial governments. Competition for scarce health care dollars to support population growth, aging, staff retention and advances in technology requires governments to pay close attention to high growth areas of the health care system.

In this chapter, the findings for the financial review are divided into the following sections:

- Overview of Total Revenues and Expenditures
- Service Cost Analysis
- Selected International Cost Comparators
- Analysis of Key Balance Sheet Items
- Assessment of the Multi-year Budget Submission Process
- Assessment of the Finance Function

Data is presented according to CBS' fiscal year which is from April to March.

3.1 Overview of Total Revenues and Expenditures

3.1.1 CBS Total Revenues

In 2001/02, CBS received a total of $791.5 million in revenue; an increase from the $688 million received in 2000/01. The primary source of revenue for CBS is the provincial/territorial governments. In 2001/02, the "member contributions" totalled approximately $640.92 million or 80.9% of total revenue.

Other revenue sources for CBS are[19]:

• Hema-Quebec for fractionated products	$94.36 million
• Unrelated Bone Marrow Donor Registry Revenue	$ 4.97 million
• Investment Income	$ 1.83 million
• Deferred Contributions	$37.46 million
• Other Income	$11.98 million

Deferred Contributions includes the portion of revenue recognized for the fiscal year for the following: transition funds, contingency funding allocated to vCJD initiatives, research and development federal funds, research and development external funds, NAT testing, Bayer Value Added Education Program, Litigation Notification Program, the Prenatal Testing Program and amortization of capital costs. The key items are further described below:

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[19] Draft, Unaudited, Non-Consolidated Statement of Operations, A Report to Canadians, 2001/02.

The MOU states that the Minister of Health (Canada) will provide $21 million over a three year period beginning in 1997/98 for administrative infrastructure, research and development costs and other costs related to the transition to a renewed blood system. The MOU further states that the Minister of Health (Canada) will also make available $60 million over 1998/99 and 1999/00 in support of transitional activities, including infrastructure costs, which satisfy the need for national integration and safety for the benefit of Canadians, including an internal capacity to respond in a timely manner to health and safety emergencies.

The MOU allows for a $25 million contingency fund for use in emergency situations. CBS has used some of this funding in the past to support initiatives related to vCJD deferrals.

The MOU specifies that the federal government would provide CBS with $5 million per year in research and development funding beginning in 2000/01.

Please note that the revenue figures stated above are taken from CBS' final, published audited statements. Final financial statements were not available when the study began. The analysis of expenditures was based on draft estimates so there may be slight differences in some of the figures.

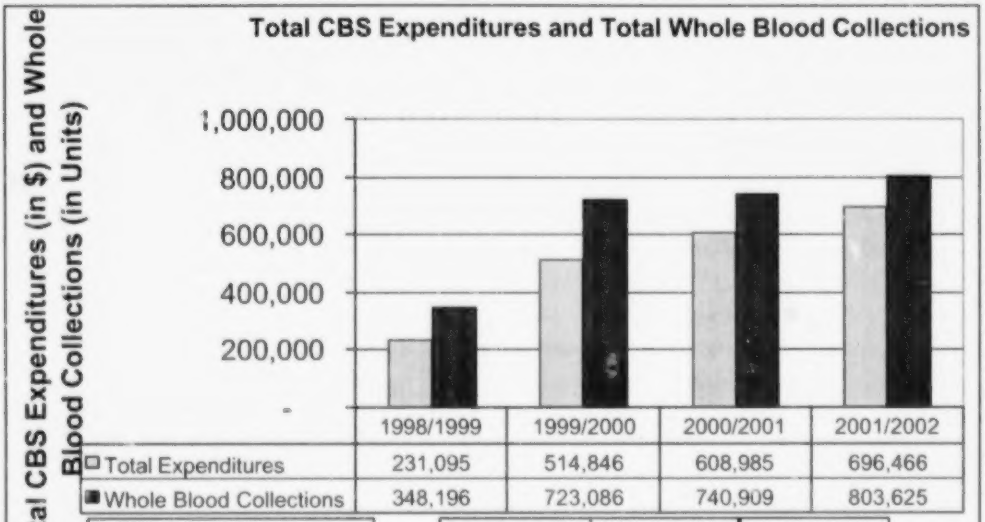
3.1.2 CBS Total Expenditures

In 2001/02, CBS reported total expenditures of approximately $790 million. This includes $103 million in fractionated product costs for Hema-Quebec and other customers. When this item is removed, total CBS expenditures for 2001/02 were $687,125,356.

CBS has been experiencing a significant increase in expenditures every year since its inception. Expenses (excluding fractionation costs for Hema-Quebec) grew by 13% between 2000/01 and 2001/02. Similar increases were experienced in prior years.

In the blood supply industry, the number of whole blood units collected from donors is a commonly used unit of activity. The graph below shows trends in expenditures and whole blood collections. Total Whole Blood Collections have been increasing steadily but not at the same rate as expenditure growth. Whole blood collections increased by 2% in 2000/01 and by 8% in 2001/02. It is important to note that while whole blood collections is an often-used indicator of activity levels, it does not reflect all of the functions performed by CBS such as fractionated products and UBMDR.

Exhibit 3-1: Trends in CBS Expenditures and Whole Blood Collections



	1998/1999	1999/2000	2000/2001	2001/2002
□ Total Expenditures	231,095	514,846	608,985	696,466
■ Whole Blood Collections	348,196	723,086	740,909	803,625

% Change	98/99 - 99/00	99/00 - 00/01	00/01 - 01/02
Total Expenditures	*N/A	18.3%	14.4%
Whole Blood Collections	*N/A	2.5%	8.5%

*1999 Total Expenditures and Whole Blood Collections represent only 6 months worth of data

To assess whether this increase is "reasonable", two approaches can be taken. One approach is to ask the question, reasonable compared to what?

- Compared to overall health sector growth of 4.3% in 2001 the CBS increases are high.[20]
- Compared to a 17.7% cost increase reported by Hema-Quebec and an 18.7% cost increase reported by Sweden, the CBS increase appears consistent with similar organizations

The second approach is to examine the reasons for the increases and assess their reasonableness. To develop an understanding of the various factors that contribute to financial performance at CBS, it is necessary to take an in-depth look at each of the organization's four key service areas:

- Blood Operations
- Patient Services
- Fractionated Products
- Unrelated Bone Marrow Donor Registry

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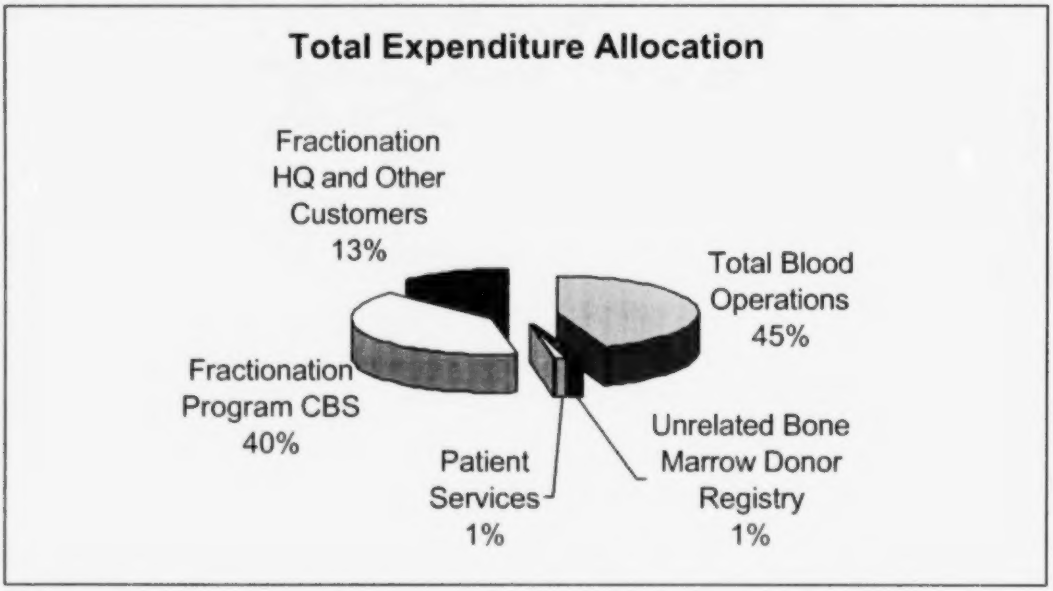
[20] Canadian Institute for Health Information website.

At a high-level, the table and diagram below illustrate the size of each of these service areas and the proportion that each one represents of the entire CBS operation.

Exhibit 3-2: Expenditures by Service Area

Expenditures	2001/2002 ($)	2000/2001 ($)
Blood Operations	351,498,357	306,664,455
Patient Services	11,349,980	10,593,427
Fractionation Program - CBS	312,686,980	281,200,286
Fractionation Program - Hema-Quebec and Other Customers	103,702,025	77,503,220
Unrelated Bone Marrow Donor Registry	11,590,039	10,461,370
Total Expenditures	**790,827,381**	**686,422,758**

Exhibit 3-3: Proportion of Expenditures by Service Area



3.2 *Service Cost Analysis*

This section will explore costs (labour, supplies and other costs), cost drivers and activity levels in detail for each of the four service areas. It is important to note that, for many areas it will only be possible to examine changes over the last two fiscal years. There have been a number of modifications to the accounting methodology at CBS over the years that make it difficult to do reliable longer-term trending. They include:

- Prior to April 1, 2000, CBS was not tracking labour hours in the General Ledger. Because labour is such a significant component of the total cost, it is difficult to explain changes in year over year expenditures in terms of price and volume components. As a result, comparisons to prior year data are not as good.
- CBS has undergone several organizational changes over the past three years. Functions that previously reported to the blood collection centres have been centralized. As a result comparisons to prior year data at the detailed level is more difficult.

3.2.1 Blood Operations

3.2.1.1 Blood Operations Overview

Blood Operations includes those functions related to the recruitment, collection, testing, processing and distribution of blood collected from donors. All corporate service costs associated with running a blood system are also included. Blood Operations accounts for the largest portion of CBS expenditures. Total Blood Operations expenditures have increased from approximately $306 Million in 2000/01 to $351 million in 2001/02. This represents a 14.7% increase in Blood Operations.

The Blood Operations budget is primarily funded by the provinces/territories based on the actual volumes of the blood and blood components issued to hospitals in each province/territory. Investment income and other income(see section 3.1.1) also contribute to Blood Operations.

Exhibit 3-4: Change in Blood Operations Costs and Units Collected

	2001/02	2000/01	% Increase
Total Blood Operation Costs	$351 Million	$306 Million	14.7%
Total Blood Collection Units[21]	882,477 Units	819,874 Units	7.1%

A comparison of the growth in Blood Operations expenditures relative to the growth in the units of blood collected shows that while expenditures have increased by 14.7% the units of blood collected have only increased by 7.1%. Clearly, there are other factors at play which are contributing to the growth in Blood Operations.

To examine these factors, Blood Operations has been divided into several functional areas and costs have been identified for each area. This is not how CBS normally reports their financial data. The source of the data in the table below was the CBS response to the international benchmarking survey.

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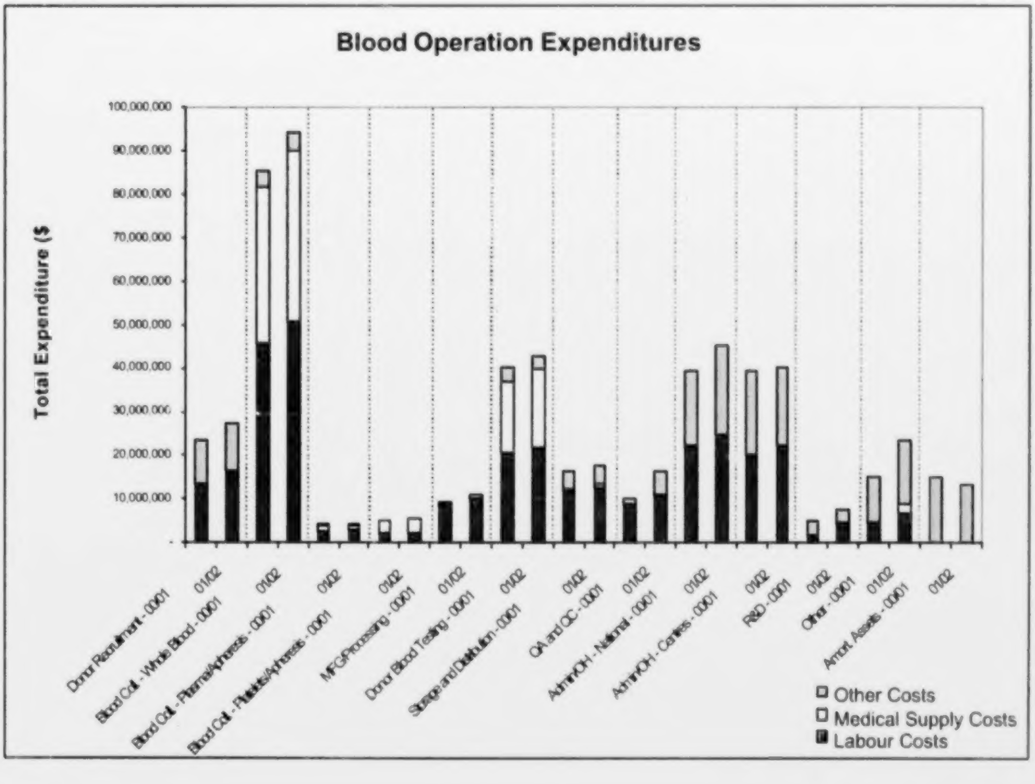
[21] The number of units presented in this table is the sum of the units for the various blood components collected (e.g. whole blood, plasma and platelets).

Exhibit 3-5: Blood Operations Expenditures by Functional Area

	2002 Cost ($)	2001 Cost ($)	Difference	% Change
Donor Recruitment	27,353,449	23,487,435	3,866,014	16%
Blood Collections - Whole Blood	94,227,625	85,367,737	8,859,888	10%
Blood Collections - Plasma via Plasmapheresis	4,462,762	4,382,697	80,065	2%
Blood Collections - Platelets via Cytapheresis	5,622,465	4,963,720	658,745	13%
Manufacturing/Processing	10,850,991	9,230,203	1,620,788	18%
Donor Blood Testing	42,793,563	40,100,201	2,693,362	7%
Storage and Distribution	17,623,757	16,396,643	1,227,114	7%
Quality Assurance and Quality Control	16,483,949	10,206,137	6,277,812	62%
Administration/Overhead - National Level	45,183,392	39,527,203	5,656,189	14%
Admin./Overhead - All Regional Blood Centres	40,231,729	39,271,727	960,002	2%
Research & Development	7,797,623	5,240,430	2,557,193	49%
Amortization of Capital Assets and Gain/Loss on Disposal of Assets	15,127,359	13,518,656	1,608,703	12%
Other Blood Operation Costs	23,739,693	14,971,666	8,768,027	59%
Total Blood Operation Costs	351,498,357	306,664,455	44,833,902	15%

Exhibit 3-6: Blood Operations Expenditures by Functional Area and Cost Category



The data above shows that there were cost increases in all areas of Blood Operations. In terms of absolute dollars, the largest cost increases have occurred in:

- Donor Recruitment ($3.9 million increase)
- Whole Blood Collections ($8.9 million increase)
- Administration and Overhead at the National Level ($5.7 million increase)
- Quality Assurance/Quality Control ($6.3 million increase)
- Other Costs ($8.8 million increase).

The following section identifies the factors that appear to be driving the cost increases in Blood Operations.

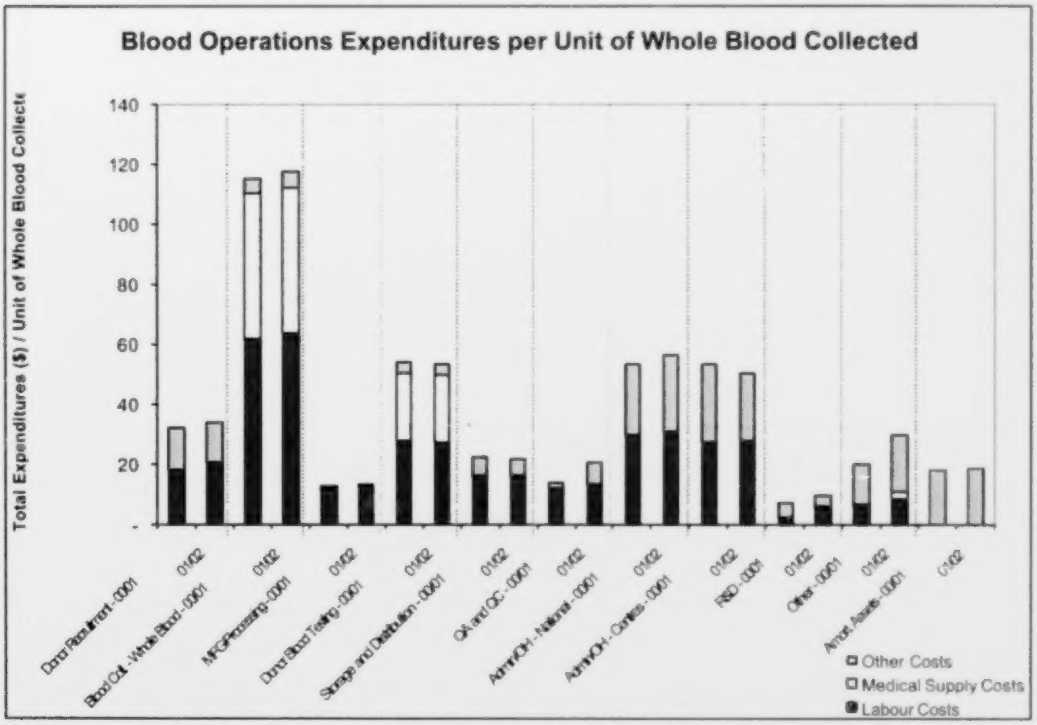
3.2.1.2 Blood Operations Cost Drivers

Demand for Blood Products

The graph below presents the expenditures for each functional area relative to the volume of whole blood collections as a measure of activity. When the data is presented in this manner, the variance between the two fiscal years is not as drastic. This suggests that at least part of the expenditure increase from one year to the next is attributable to increased blood collections.

CBS is continually trying to increase the units of blood collected in order to keep pace with the hospitals' growing demand for blood and blood components. The volume of blood and blood components shipped to hospitals has been increasing each year. The volume of hospital shipments increased by 4.6% from 1999/00 to 2000/01 and by 5.3% from 2000/01 to 2001/02.

Exhibit 3-7: Blood Operations Expenditures per Whole Blood Unit



Regulatory Requirements and Other Safety Improvements

Blood Operations costs are also impacted by regulatory requirements and other safety improvements. Regulatory requirements and safety improvements drive Blood Operations costs because of their effect on medical supply costs and/or staffing (i.e. labour hours).

Medical supply costs for Blood Operations experienced a 12% increase from $60.6 million in 2000/01 to $68.1 million in 2001/02. CBS explains the $7.5 million increase in medical supply costs as follows:

- $1.8 million related to the implementation of NAT HIV testing on May 28th 2001
- $4.6 million related to volume
- $0.2 million related to price increases
- $0.6 million in R&D

The costs of the NAT-HCV and NAT-HIV test kits are approximately $5,200 and $1,600 respectively. The large difference in the cost of the two kits is due to the imposition of a royalty fee on the NAT-HCV test kit. Each test kit contains 48 tests, therefore, the cost per test is $109 for HCV and $33 for HIV. The $109 per test for HCV includes $75 in royalty fees. The royalties on HCV test kits started on February 15, 2002. The full impact of the royalty fees will be seen in 2002/03. It is also important to note that the $1.8 million related to HIV testing corresponds to 10 months of activity and that CBS reports that additional cost increases will materialize in 2002/03 when the program is fully operational for 12 months.

Another example, worth noting is the introduction of universal leukoreduction in 1999, in response to a directive from Health Canada. This had a significant impact on Blood Operations cost in the 1999/00 fiscal year. The special filter-equipped blood bags required for leukoreduction resulted in a price increase from $7 per bag to $42 per bag – a difference of $35 per bag that must be attributed to every unit of blood collected. In 1999/00, 723,086 units of whole blood were collected. The cost impact of the leukoreduction bags, allowing for a 5% wastage factor, would have been $26.6 million.

An example of how regulatory requirements can affect staffing is manual expiry date labelling. Manual expiry date labelling was a regulatory requirement implemented on October 1, 2001 to ensure that blood components did not exceed the recommended amount of storage time that would render the blood component unusable. This has resulted in the addition of 32 Full-Time Equivalents to complete the tasks required to label each Blood Collection bag with the date and time of expiration of Blood Components. (Manual expiry date labelling is temporary. With the implementation of the new MAK information system, this function will become obsolete as the MAK system will track the expiration dates automatically.) An increase in the number of staff (full time equivalents) results in an increase in labour hours.

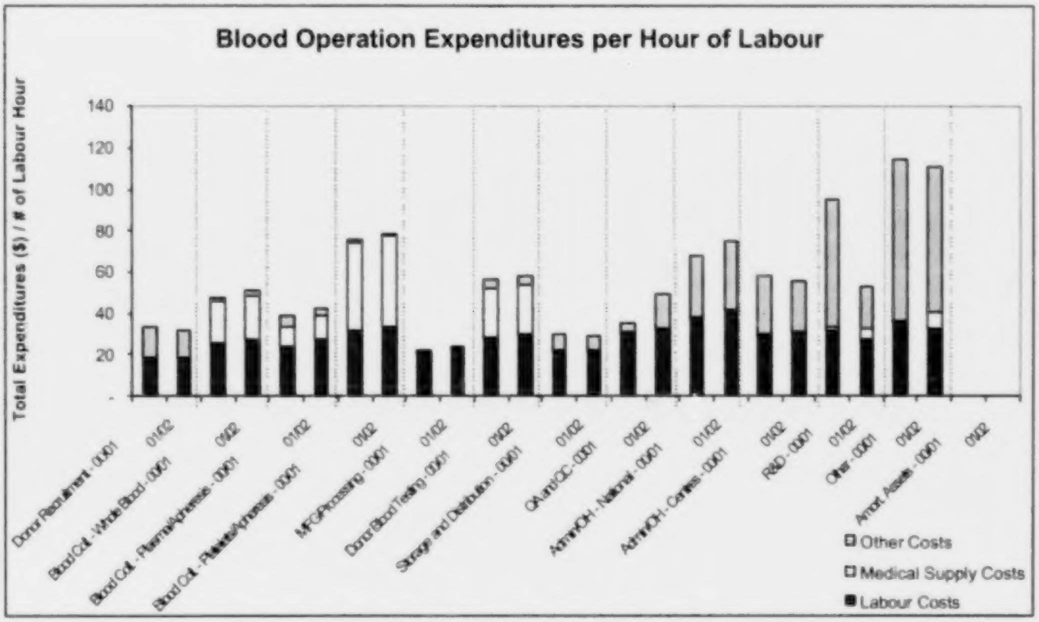
The table below shows total labour hours for each functional area for 2000/01 and 2001/02. From 2000/01 to 2001/02 there was a 10% increase in labour hours for Blood Operations and a 9% increase in labour hours for the organization as a whole. The only functional area that did not experience an increase in labour hours was Blood Collections for plasma via plasmapheresis. The areas that experienced the largest percentage increase in labour hours were research and development (166%), other costs (63%) and donor recruitment (23%). The variance in research and development labour hours appears to be due to the implementation of new research projects.

Exhibit 3-8: Blood Operations Labour Hours by Functional Area

	2001/2002 Labour Hours	2000/2001 Labour Hours	Difference	% Change
Donor Recruitment Labour Hours	867,442	704,907	162,535	23%
Blood Collections - Whole Blood Labour Hours	1,845,156	1,782,923	62,233	3%
Blood Collections - Plasma via Plasmapheresis Labour Hours	104,554	113,999	-9,445	-8%
Blood Collections - Platelets via Cytapheresis Labour Hours	71,324	65,666	5,658	9%
Manufacturing/Processing Labour Hours	450,988	414,824	36,164	9%
Donor Blood Testing Labour Hours	733,183	714,070	19,113	3%
Storage and Distribution Labour Hours	596,431	551,165	45,266	8%
Quality Assurance and Quality Control Labour Hours	331,963	290,213	41,750	14%
Administration/Overhead - National Level Labour Hours	604,006	585,710	18,296	3%
Admin./Overhead - All Regional Blood Centres Labour Hours	724,154	679,659	44,495	7%
Research & Development Labour Hours	146,346	55,119	91,227	166%
Other Blood Operation Labour Hours	213,204	130,472	82,732	63%
Total Blood Operation Labour Hours	**6,688,751**	**6,088,727**	**600,024**	**10%**
Patient Services Labour Hours	**280,998**	**295,665**	**-14,667**	**-5%**

The following graph shows Blood Operations expenditures per hour of labour for each functional area. In this analysis there is very little difference from year to year, suggesting that increased labour hours are a contributor to the overall increase in Blood Operations expenditures.

Exhibit 3-9: Blood Operations Expenditures by Labour Hour

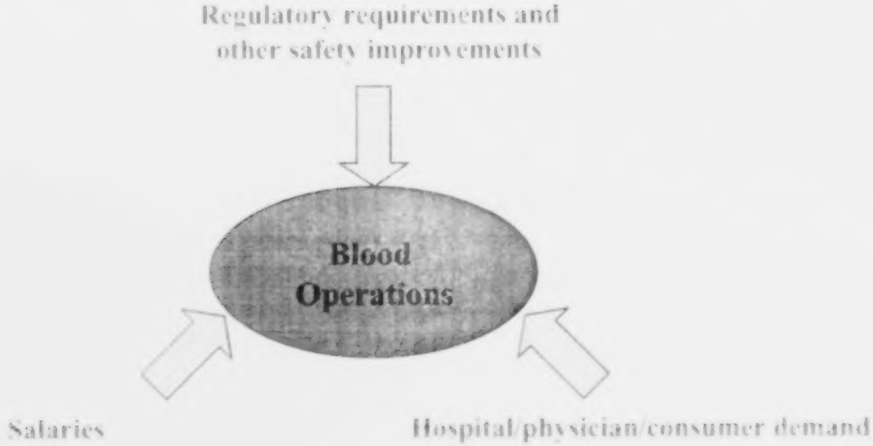


Salary Costs

Approximately 70% of CBS staff are unionized. Because the Blood Centres are located in the various provinces, the unionized staff in the Centres are governed by provincial collective bargaining agreements. There are currently 29 different collective bargaining agreements that cover the staff at CBS. This is an area over which CBS has little control because they are under strong pressure to accept the salary rates and conditions negotiated at the provincial level. CBS reports that the salary increases necessitated by the collective agreements can range from 1% to 10% per year with an average annual step increase of approximately 4% per year. The increase in salary costs was 8.6% between 2000/01 and 2001/02. This represents a weighted average across all union groups.

The diagram below summarizes the key cost drivers for Blood Operations.

Exhibit 3-10: Blood Operations Cost Drivers


Regulatory requirements and other safety improvements
Blood Operations
Salaries
Hospital/physician/consumer demand

The next sub-sections will examine each function within Blood Operations.

3.2.1.3 Donor Recruitment

Donor recruitment costs increased by approximately $3.9 Million from 2000/01 to 2001/02. The main components of this increase were:

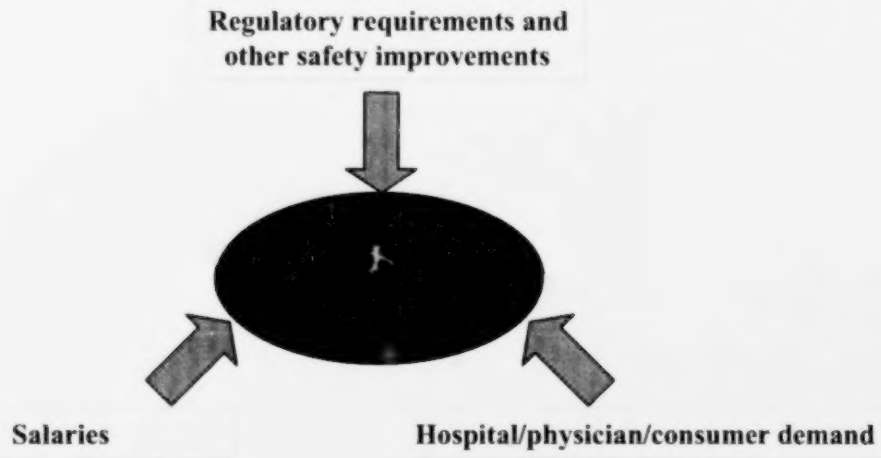
Increased telerecruting and donor service staff	$2,500,000
Salary Increases	$ 315,600
Severance Costs	$ 226,700
Increased Administrative Costs	$ 504,300

CBS reports that in 2000/01, the call centre located in Toronto was not fully operational, therefore the increase in costs when compared to 2001/02 reflect the "ramp-up" of the call centre. In addition, the telerecruitment costs reflect significant activities related to the vCJD deferral, which may not be consistent between the two fiscal years.

The detailed breakdown of donor recruitment costs is shown below.

The diagram below summarizes the key cost drivers for Blood Operations.

Exhibit 3-10: Blood Operations Cost Drivers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The detailed breakdown of donor recruitment costs is shown below:

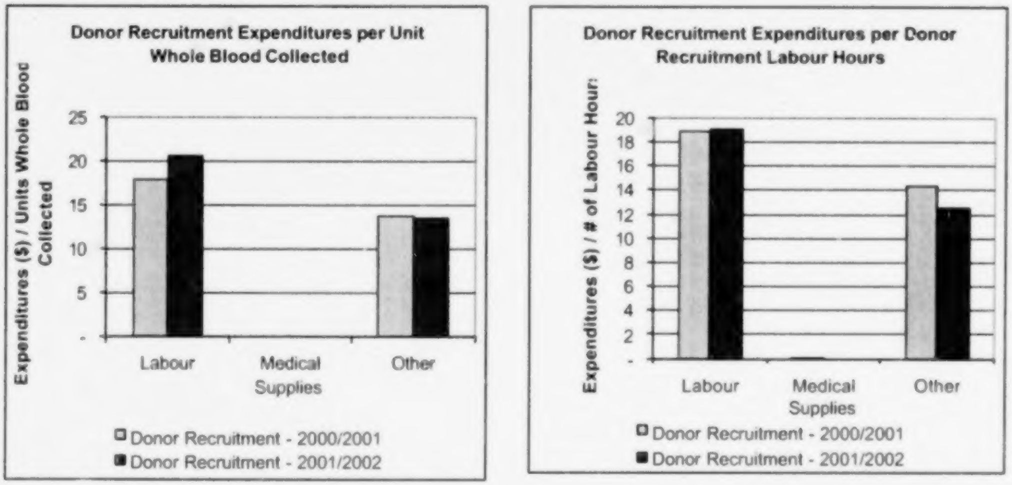
Exhibit 3-11: Breakdown of Donor Recruitment Costs

Donor Recruitment Costs	2001/2002	2000/2001	Change	% Change
Staff Costs	16,509,823	13,324,333	3,185,490	24%
Medical Supplies	1,650	8,826	(7,176)	-81%
Clinic Costs	2,443,513	2,234,663	208,850	9%
Travel	496,270	517,280	(21,010)	-4%
Admin. Services	6,219,960	5,705,433	514,527	9%
Professional Fees	808,823	683,486	125,337	18%
Other Purchased Services	684,914	722,318	(37,404)	-5%
Property Expenses	80,557	88,986	(8,429)	-9%
Equipment	90,863	191,250	(100,387)	-52%
Misc expense - Costs Recovery	17,075	10,859	6,216	57%
Total Costs	**$ 27,353,448**	**$ 23,487,434**	**$ 3,866,014**	**16%**

The graphs below show that

- Donor Recruitment Costs Per Unit of Whole Blood Collected had a notable increase from 2000/01 to 2001/02, suggesting that Donor Recruitment Costs increased at a higher rate than the increase in collections
- Donor Recruitment Costs per Donor Recruitment Labour Hour has been quite stable over the past two fiscal years. This implies that the increase in Donor Recruitment expenditures has been in proportion to an increase in labour hours. Donor recruitment labour hours increased by 23% from 2000/01 to 2001/02.

Exhibit 3-12: Donor Recruitment Costs per Unit Collected and per Labour Hour



CBS has had to invest in donor recruitment to maintain the donor base in light of vCJD deferrals. Also, a key goal of the organization is to increase the percentage of active donors from 3.6% of the eligible population to 5% of the eligible population. Although it is not surprising that donor recruitment costs increased at a higher rate than collection costs, the increases in donor recruitment costs should be monitored and measured relative to the benefits.

The cost-effectiveness of donor recruitment must be assessed relative to the change in collection volumes. According to CBS, the "one goal" for donor recruitment is "a stable and consistent national supply of blood and blood products available at the right time and right place."[22]

In 2000/01, the total recruitment costs per unit of blood collected was $28.64. In 2001/02, it was $31.00, an 8% increase in unit cost. Also, the increase in expenditures of $3,866,014 resulted in an increase of 62,603 units of blood. This was attained at a cost per unit of $61.75 for the additional units.

The recruitment strategy is not only about investing. One of the aspects of the centralized franchise/retail model that CBS has developed is "efficiencies due to economies of scale". The unit cost figures above do not demonstrate efficiency gains in donor recruitment. Initiatives such as consolidation of call centre activities would be expected to reduce costs in donor recruitment in the future.

The limitations of this analysis are that some of the recruitment programs may have longer term benefits not realizable in a single year (e.g. programs aimed at high school students). This has always been the case but if there is more emphasis on awareness programs in a particular year it makes year-to-year comparisons difficult.

Another issue is that last year CBS consolidated all regional telephone expenses at the National level. Therefore, tele-recruitment telephone expenses are reflected under National Administration/overhead, rather than under donor recruitment.

Recommendation #23: To ensure cost-effectiveness, donor recruitment should be monitored closely from the perspective of costs versus outcomes/benefits. Savings and other performance measures related to the establishment of the National Contact Centre should be tracked and reported.

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[22] Coach's Corner, Defining the Positions/Roles on Team Xtreme, Marketing and Communications Strategic Direction 2002, page 2.

3.2.1.4 Collection of Whole Blood

Whole Blood Collection costs increased by approximately $8.9 million from 2000/01 to 2001/02 – a 10% increase. Over the same timeframe, the volume of whole blood collected increased by 8.5%. The table below shows that the majority of the variance is due to increases in labour costs and medical supplies, which amounted to an increase of approximately $5.3 million and $3.3 million respectively. Labour costs were affected by Collective Bargaining Agreements, which increased salary costs by $3.9 million. An increase in labour hours to handle the increased collections accounts for the remaining $1.4 million variance in labour costs. Labour hours increased by 3%.

Medical supplies for Collections increased by $3.3 million. Much of this can be attributed to the increase in the volume of collections. The volume of Collections increased by 8% or 62,716 units from 2000/01 to 2001/02. Every unit of blood collected requires a blood bag which cost approximately $42. Therefore, the increase in blood bag expenses would amount to over $2.7 million. The rest of the increase in medical supply costs is attributed to inflation (approximately $0.2 million) and other miscellaneous medical supplies (approximately $5 per unit).

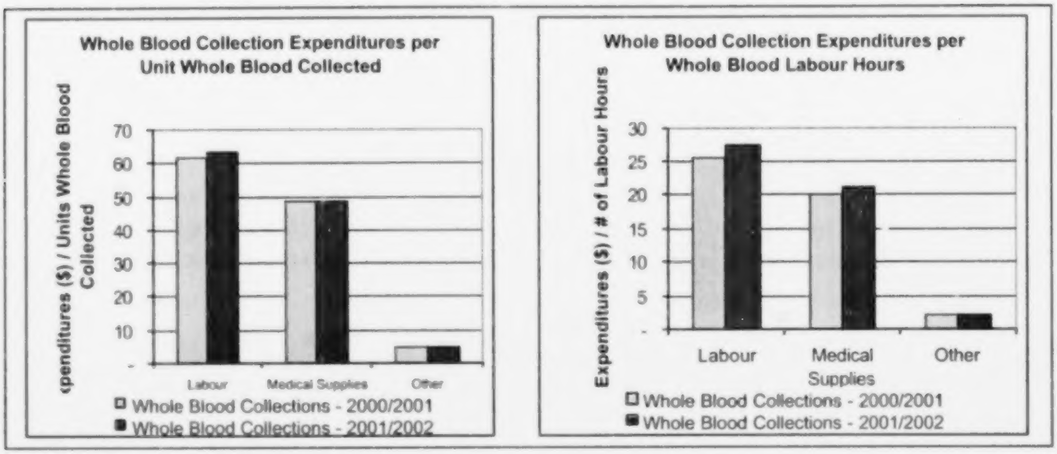
Exhibit 3-13: Breakdown of Whole Blood Collection Costs

Whole Blood Collection Costs	**2001/2002**	**2000/2001**	**Change**	**% Change**
Labour Costs	50,832,860	45,534,683	5,298,177	12%
Medical Supplies	39,310,604	36,032,870	3,277,734	9%
Clinic Costs	2,154,910	2,016,388	138,522	7%
Travel	292,615	287,104	5,511	2%
Admin. Services	636,968	414,751	222,217	54%
Professional Fees	3,039	2,863	176	6%
Other Purchased Services	240,694	272,262	(31,568)	-12%
Property Expenses	439,092	553,391	(114,299)	-21%
Equipment	316,127	252,499	63,628	25%
Misc expense - Costs Recovery	716	925	(209)	-23%
Total Costs	**$ 94,227,625**	**$ 85,367,736**	**$ 8,859,889**	**10%**

The graphs below show that:

- The Collection Cost per Unit of Whole Blood Collected experienced a small increase from 2000/01 to 2001/02 from $115.22 to $117.25 (a 1.7% increase).
- There was a slightly larger increase in Collection Cost per Labour Hour from 2000/01 to 2001/02. Collection labour costs increased from $61 per Unit to $63 per Unit - a 3% increase. According to CBS, the average salary increase for unionized staff was 8%.
- Medical supply costs per unit and other costs per unit of whole blood are consistent across the two fiscal years.

Exhibit 3-14: Collection Costs per Unit Collected and per Labour Hour



CBS data suggests that the whole blood collection function realized efficiency gains between 2000/01 and 2001/02. Labour hours per unit decreased from 2.41 to 2.30. At a labour rate (cost per labour hour) of $27.55, this efficiency gain translates to savings of $2.4 million.

Recommendation #24: A large component of blood collection costs is the cost of the blood bags equipped with special filters for leukoreduction. The bags costs approximately $42 each and CBS estimates a 5% wastage factor. It is recommended that a performance target be established to reduce the blood bag wastage factor. Given current collection volumes, just reducing the wastage factor by one percent (i.e. to 4%) would result in savings of about $340,000.

3.2.1.5 Quality Assurance/Quality Control

From 2000/01 to 2001/02, expenditures on Quality Assurance/Quality Control increased by $6.3 million or 62%.

One of the challenges in interpreting QA/QC expenditures is that this functional area includes both ongoing, regular QA/QC activities and a number of large special projects.

Exhibit 3-15: Breakdown of Quality Assurance/Quality Control Costs

QA/QC Costs	2002	2001	Change	% Change
Labour Costs	10,490,515	8,671,334	1,819,181	21%
Medical Supplies	369,727	374,151	(4,424)	-1%
Clinic Costs	289	312	(23)	-7%
Travel	1,142,152	494,496	647,656	131%
Admin. Services	250,716	265,971	(15,255)	-6%
Professional Fees	4,028,604	201,549	3,827,055	1899%
Other Purchased Services	121,466	151,088	(29,622)	-20%
Property Expenses	-	4,294	(4,294)	-100%
Equipment	66,510	42,943	23,567	55%
Misc expense - Costs Recovery	13,970	(2)	13,972	-698600%
Total Costs	**$ 16,483,949**	**$ 10,206,136**	**$ 6,277,813**	**62%**

The table above shows that the largest component of the variance was a $3.8 million increase in professional fees. According to CBS, the largest components of the professional fee increase are the Change Control initiative and the System Wide Validation Initiative. The Professional Fees incurred for the Change Control initiative were $2.3 million and $1.3 million for the System Wide Validation initiative – a total of $3.6 million of the $3.8 million in professional fee variance.

The Change Control initiative is one of the Transformation projects. It refers to the establishment of a policy that will assure all changes will be controlled by evaluating, approving and monitoring all changes that may impact CBS operations. The professional fees identified relate to the development of 16 SOPs from six policies. There were multidisciplinary staff engaged in the systems/SOPs development and training programs were designed for each policy/procedure. Specifically, professional fees for the Change Control Project related to the following list of services:

General Services:

- General Consulting on GMP, Validation and Regulatory Compliance matters
- Telephone consultations
- Documentation review
- Document preparation
- US Food and Drug Administration (FDA) assistance: Consulting on FDA communication and interaction
- Meetings
- Other services (as identified and requested by CBS)

Specific services:

- Mock pre-approval inspection (PAI)/GMP Audits/On-site visits/Gap analysis
- Training Programs/Activities

- Design review
- Corrective action plan (CAP) preparation
- Validation Master Plan (MVP) review/development
- Validation Policy and Procedure review/development
- Qualification Protocol Development
- Equipment/System Qualification Testing
- Qualification Final Report Development
- Other services (as identified and requested by CBS)

GMPWare ™ Software-related Services:

- Installation
- Training
- Guidelines/Standards
- Other Services (as identified and requested by CBS)

Additional Services:

- Providing CBS with draft-related policies and procedures for document control, process change control, and computer change control documents
- Development of a Documentation Management System
- Documentation Management for CBS Documentation Department via telephone.
- Providing compliance opinions on US FDA regulatory requirements related to Documentation Management.
- Change Control Manager on-site in Ottawa, for up to six months
- Design and implementation of CBS' Training System Implementation Plan
- Development of a CBS' Quality Non-Conformance System Implementation Plan
- Develop CBS' Validation System Implementation Plan and associated training program

With respect to the System Validation Project, professional fees were for:

- Validation of the new Winnipeg Blood Centre
- Writing of the Master Validation Plan
- Writing protocols and training CBS Centre staff on protocol execution
- Contractor on site for Health Canada pre-licensing audit as well as meetings with Health Canada for Master Validation Plan "walkthrough"

The remaining Validation Project professional fees were for routine CBS validation requirements (premises e.g. Alarm/Data Monitoring Systems (ADMS), HVAC and miscellaneous equipment).

The Change Control initiative is very broad in scope. The professional fees of $2.3 million would translate to 920 person days of service based on a per diem rate of $2,500 per day (typical per diem for a senior consultant). This equates to approximately four senior individuals working full-time on the initiative for the entire year. Similarly, the professional fees of $1.3 million for the System Validation Project translate to 520 person days of service based on a per diem rate of $2,500 or approximately two full-time individuals. The reasonableness of these expenditures would depend on the specific work products produced, the processes used, consultant qualifications relative to per diem rates, etc. A detailed examination of these factors was not conducted within the scope of this review. Also, there are no benchmarks to which these initiatives can be compared. However, the professional fee expenditure is high and Members should ensure that detailed reports on project outcomes are available.

The second largest contributor to the cost variance in QA/QC was labour costs which increased by over $1.8 Million. Collective bargaining and salary increases accounted for $747,800 of the increase in labour costs. The remaining variance is mainly due to an increase in staffing. According to CBS, an increase in staffing was required to bring the ratio of Quality Assurance and Quality Control staff to Production staff in line with industry benchmarks. The Safety & Performance Management division of CBS prospectively benchmarked the ratio of QA staff to production staff using a standard telephone survey by experienced professional QA/Production staff. According to CBS, the purpose of the survey was to aid the required creation of an independent, identifiable, authoritative QA function in CBS, where none had previously existed.

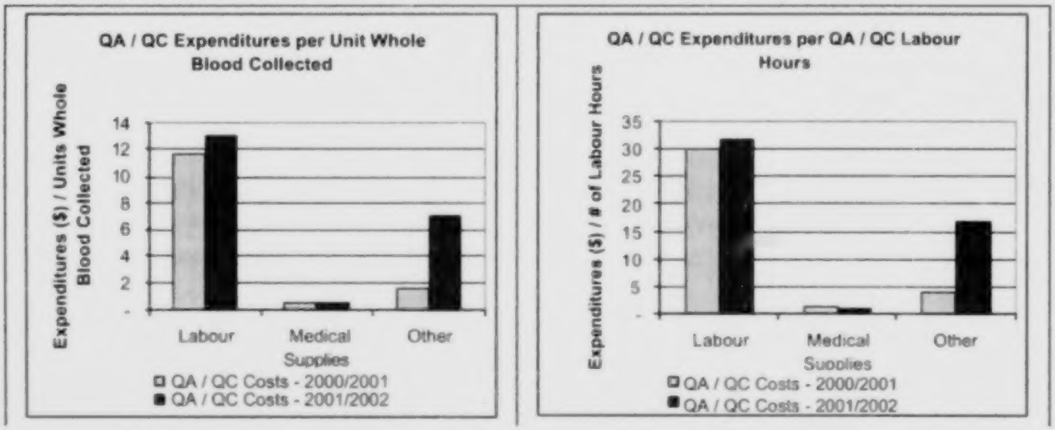
This survey compared pharmaceutical industry (USA/Canadian) representative organizations with blood industry (USA/Canadian) representative organizations. Those surveyed in the USA blood industry where US FDA consent-decree provisions are in place were identified. The survey included five pharmaceutical companies, six blood operators and Hema-Quebec. The results show that all of the blood operators had a significantly lower ratio of QA staff to production staff than the pharmaceutical companies. Amongst the blood operators, three blood operators (including Hema-Quebec) had a higher ratio than CBS. The other four blood operators surveyed had a lower ratio than CBS. Based on these results, CBS made the decision to increase QA/QC staff. Quality Assurance and Quality Control labour hours increased by 14% between 2000/01 and 2001/02.

Travel costs for QA/QC were $1.1 million in 2001/02. This is an increase of $647,656 which CBS reports was mainly due to travel costs for two initiatives -- Change Control ($284,000) and System Wide Validation ($293,000). These costs are high (i.e. over $1,100 per work day for each project) and warrant further investigation. (It was beyond the scope of this review to analyze individual travel expense claims in terms of who travelled where, why and how often).

Recommendation #25: The professional fees and travel costs for the Change Control Initiative and the System Validation Project are substantial. CBS should provide the Members with detailed reports on the progress of these initiatives including the outcomes produced relative to the costs incurred.

The first graph below show the relationship between QA/QC costs and collection units. It supports the explanation provided above that the cost increase in QA/QC is due primarily to a substantial increase in other costs (e.g. professional fees) and secondarily to increased staffing and salaries. This is reinforced in the second graph which examines QA/QC costs per QA/QC labour hours. The labour cost per labour hour increased slightly (due to the salary increases). The other costs per labour hour increased more dramatically since the other cost increases were related to professional fees which do not impact on CBS labour hours.

Exhibit 3-16: Quality Assurance/Quality Control Costs per Unit Collected and per Labour Hour



3.2.1.6 Administration / Overhead – National Level

CBS reports two types of Administration/Overhead costs – national level costs and regional/Centre level costs. This section discusses national level costs.

Administration/Overhead at the National Level increased substantially by $5.7 million from 2000/01 to 2001/02. This represents a 14% increase.

Exhibit 3-17: Breakdown of National Administration/Overhead Costs

Administration / Overhead National Level Costs				
	2001-2002	**2000-2001**	**Incr/Decr**	**% Incr/Decr**
Labour Costs	24,943,792	21,852,907	3,090,885	14%
Medical Supplies	24,709	276,977	(252,268)	-91%
Clinic Costs	9,155	7,291	1,864	26%
Travel	2,557,634	2,879,949	(322,315)	-11%
Admin. Services	7,726,658	5,324,389	2,402,269	45%
Professional Fees	4,634,566	3,963,871	670,695	17%
Other Purchased Services	2,327,671	1,881,559	446,112	24%
Property Expenses	2,389,403	2,703,799	(314,396)	-12%
Equipment	331,374	363,594	(32,220)	-9%
Misc expense - Costs Recovery	238,430	272,866	(34,436)	-13%
Total Costs	**$ 45,183,392**	**$ 39,527,202**	**$ 5,656,190**	**14%**

The table above illustrates that the most notable increase was in Administration Services (45% increase). According to CBS, this increase was due to a change in accounting for telephone expenses between the Centres and Head Office. As part of the Transformation strategy, CBS consolidated all telephone expenses to the Head Office. This resulted in an increase of $1.8 million in telephone expenses for Head Office. ($1.4 million of this reallocation was offset in the Regional Centre Administration/Overhead budget.) CBS reports that the $400,000 difference can be attributed to the increased telerecruitment activity involved in bringing in new donors due to the vCJD concerns and to increase collections by 7% due to increasing demand.

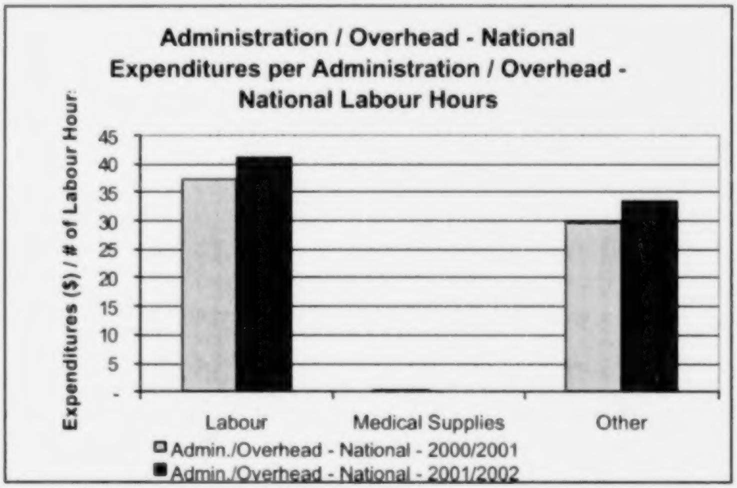
The increase in Administrative Services is also due to higher premiums in insurance ($244,000 increase) and higher costs of promotional materials ($300,000). The combination of these factors account for the increase of $2.4 million in Adminstration/Overhead at the National Level.

Labour costs under Administration/Overhead increased by over $3 million. Information provided by CBS indicates that salary increases and collective bargaining agreements account for $2.3 million of this variance. The average salary increases were 5.5% for non-unionized staff and 8.6% for unionized staff (across all union groups in the organization). There was also an increase of 7.36 FTEs from 2000/01 to 2001/02 which increased labour costs by approximately $489,000. The 7.36 FTE increase was primarily related to Information Services. The staff were for the SAP support group and the Help Desk. The increase in the Help Desk FTEs was the result of the consolidation of support functions in Ottawa. As a result, there were decreases in Computer Services FTEs in the Centres. Labour hours increased by 3%. Due to CBS restructuring, an additional $520,000 was incurred for severance payments. Staff recruitment costs also increased by $178,000.

CBS has saved costs in certain Administration/Overhead areas such as medical supplies, travel, property expenses, equipment and miscellaneous expenses (Costs /Recovery). Net savings in these areas has resulted in $956,000 cost savings.

The graph below shows an increase in Administration/Overhead Costs per Labour Hour. This suggests, in keeping with the above discussion, that the increase in Administration/ Overhead is due to factors other than just labour.

Exhibit 3-18: National Administration/Overhead Costs per per Labour Hour



Recommendation #26: The financial review revealed unexpected high expenditures in the areas of administration/overhead, travel and professional fees. It is recommended that Members and P/T Contacts closely monitor these cost items in CBS reports and if necessary, request a detailed audit of these costs before increased investment is made in these areas

3.2.1.7 Administration / Overhead – All Regional Centres

Regional Centre Administration/Overhead showed an increase of $960,000 or 2%. Administrative/Overhead staff costs in the Regional Centres increased by over $2.2 million. According to CBS, the impact of salary increases and collective bargaining agreements has resulted in labour costs increasing by $390,000. There was also an increase of 22.8 FTEs from 2000/01 to 2001/02 which increased labour costs by approximately $749,000. Labour hours increased by 7%. Due to CBS restructuring, an additional $964,000 was incurred for severance payments. Increased staff training costs of $135,000 were also incurred. In the area of Administrative Services, there was an decrease from 2000/01 to 2001/02 of $1,593,484. This was largely due to the reallocation of telephone expenses to the Head Office budget ($1.4 million). Administrative Services also decreased because of a $158,000 reduction in photocopying costs.

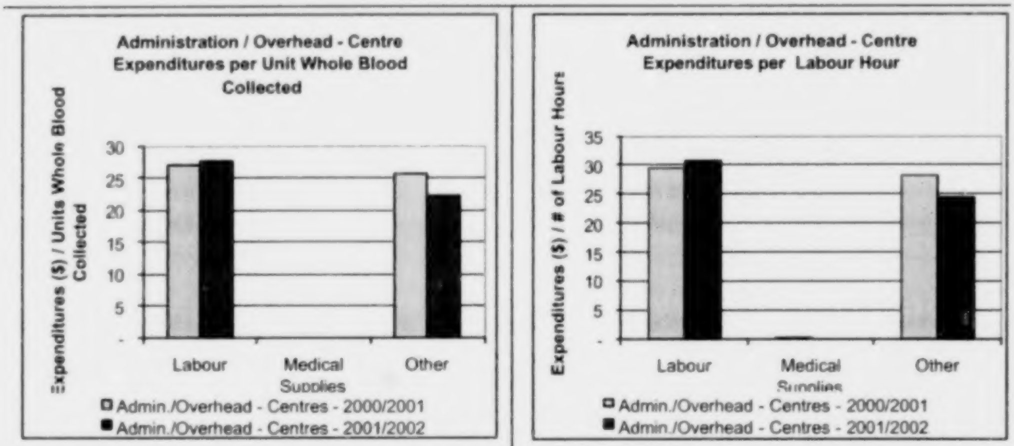
At the Regional Centre level, CBS has saved costs in certain areas such as medical supplies, travel, professional fees, and equipment. Net savings in these areas amounted to $1.9 million.

Exhibit 3-19: Breakdown of Regional Centre Administrative/Overhead Costs

Administrative / Overhead Regional Centre Costs				
	2001-2002	**2000-2001**	**Incr/Decr**	**% Incr/Decr**
Staff Costs	22,359,302	20,112,300	2,247,002	11%
Medical Supplies	38,594	45,996	(7,402)	-16%
Clinic Costs	91,320	83,925	7,395	9%
Travel	554,180	659,904	(105,724)	-16%
Admin. Services	3,513,131	5,106,615	(1,593,484)	-31%
Professional Fees	1,728,353	1,844,217	(115,864)	-6%
Other Purchased Services	2,288,263	2,068,666	219,597	11%
Property Expenses	9,430,584	9,117,622	312,962	3%
Equipment	208,734	279,914	(71,180)	-25%
Misc expense - Costs Recovery	19,267	(47,431)	66,698	-141%
Total Costs	**$ 40,231,728**	**$ 39,271,728**	**$ 960,000**	**2%**

The graphs below reflect that the "other costs" within Administration/Overhead Cost Per Unit of Collection has gone down due to cost reallocation at CBS.

Exhibit 3-20: Regional Administration/Overhead Costs per Units Collected and per Labour Hour



Administrative/overhead costs (for head office and the Centres) accounted for 24.1% of Blood Operations expenditures in 2000/01 and 22.8% in 2001/02. This rate is higher than expected and warrants further investigation. By comparison:

- On the international benchmarking survey, Hema-Quebec reported an administration/overhead rate of 12%
- Other health care organizations typically have lower rates; for example the Ontario Acute Care Report Card tracks a "corporate services" indicator which looks at the ratio of administrative services to total operating expenses. In 1999/00, Ontario hospitals spent 8.98% of operating dollars on administrative/overhead expenses.
- Expert panel members estimate the overhead rates at U.S. Blood Centres to be 14 to 15%

3.2.1.8 Research and Development

The MOU states that "coordinating a national program in research and development for blood, blood products and transfusion medicine" is one of the key support functions to be provided by CBS.

Research and development (R&D) is funded through provincial/territorial Members contributions, federal funding and external grants.

In 2001/02, the component of the R&D program that is funded from the provincial members' contributions had actual expenditures of $6 million relative to a budget of

$7.6 million. Favourable variances occurred in staff costs, medical supplies, administrative costs and other expenses.[23]

The MOU provides that "the Minister of Health (Canada) will make available for the NBA research and development funds in the amount of $5M annually starting in 2000-2001." CBS also obtains a small amount of research and development funds from other sources including granting agencies and donations.

Since there is a start-up period for research and development projects, only a portion of the first instalment of federal research funding was used in 2000/01. Only the funds actually used are recognized as revenue in a given year and matched against related expenses. The unused portion is identified under deferred contributions. The research and development funds are considered "restricted funds" and should only be used for research purposes.

According to the international benchmarking survey completed by CBS, total R&D expenditures in 2001/02 were $7.8 million.

Two questions have been raised about research and development. First, is the amount of research and development funding appropriate? And second, should CBS be engaged in research and development activities? Each question is addressed below:

2001/02 R&D expenditures represent about 2% of blood operations expenditures and 1% of total expenditures when fractionated products are included. By comparison, Hema-Quebec states a goal of allocating 5% of its operating budget to research and development.[24] In the international benchmarking survey, the R&D direct cost expenditures reported by Hema-Quebec were 3% of blood operations costs. R&D expenditures reported by the United Kingdom were approximately 1% of total blood operations. The American Red Cross allocates 2% of their blood program budget to research at Holland Labs (a minor amount of locally funded research is done at the Centres).[25] These comparisons suggest that the R&D costs for CBS are conservative and not out of line with other jurisdictions.

In terms of whether CBS should be engaged in R&D activities it is important to consider consistency with mandate, the nature of the activities performed, the capacity of the organization to support the activities (e.g. availability of required expertise, affordability) and the available alternatives.

- Clearly, R&D is within the mandate of CBS because it is specified as a key support function within the MOU.

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[23] Canadian Blood Services Management Report as at March 31, 2002 - Draft

[24] Hema-Quebec website.

[25] Telephone conversation with Director of the Holland Labs.

- Blood operators in other jurisdictions (e.g. Quebec, UK, U.S., Australia) also carry out R&D activities.
- CBS is involved in a number of R&D initiatives including: improved blood product storage processes, replacement products for plasma-derived proteins, studies of known or potential blood-borne infectious agents, the immunology of blood transfusion and the development of substitutes for standard red cell and platelet products. In collaboration with Hema-Quebec, CBS is exploring a different way to produce platelets called the buffy coat method. In partnership with the Canadian Institutes for Health Research, CBS is supporting research studies in the area of blood utilization and conservation.
- There are over 100 staff with diverse expertise in the R&D department. To improve the capacity of the organization to support R&D activities, a "hub and spokes" model has been implemented. According to CBS, the creation of research hubs permits the development of a critical mass of researchers working in one area of research. The spokes are formed by staff who are conducting related research but who are not physically located in a hub. The designated hubs and their teams are Ottawa (Blood-Borne Infectious Diseases), Toronto (Transfusion Immunology), Hamilton (Transfusion Clinical Trials), Edmonton (Cryopreservation for Blood and Hemotopoietic Stem Cells) and Vancouver (Blood Product Processing, Storage and Substitutes).
- CBS has not overspent its R&D budget.
- Universities and teaching hospitals across the country are also involved in R&D activities. CBS is involved with many of these research partners. For example, in January of this year, the Canada Foundation for Innovation funded a $15.1 million infrastructure grant to support the University of British Columbia's Centre for Blood Research. This is a unique centre in Canada that is dedicated to research in transfusion science. CBS is a partner with the University in this initiative. The funds will be used to build and equip new research laboratories in Vancouver where CBS scientists will work together with University of British Columbia researchers.[26]

In terms of existing funding, the British Columbia research centre is larger than the CBS R&D program and may present an alternative if the CBS Board and Corporate Members wished to divest R&D activities. There may be other institutions with significant blood research programs as well. However, if CBS were to cease provision of R&D it is assumed that the federal funding for R&D would no longer flow to CBS.

Recommendation #27: It is recommended that CBS encourage research related to governance, management, administration and operation of a blood system in addition to the clinical/technical areas that are currently the focus of CBS' research and development activities. As noted earlier, this would support policy development by the Members and CBS.

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[26] Much of the information in this section was extracted from: "On Target", Canadian Blood Services' Internal Corporate News Bulletin, Vol.1, No.6, April 2002, page 5.

Recommendation #28: The long-term role of CBS in R&D is an issue that should be discussed as part of the development of the CBS vision. The impact of various options should be assessed.

3.2.1.9 Other Blood Operations Costs

The "Other Costs" category experienced an increase of $8.8 million between 2000/01 and 2001/02 – a 59% increase. This increase is due to the increasing number of projects that CBS has been involved in.

The largest projects were the HR Payroll project and the MAK project. These two projects are funded from Transition funds, not from annual Members Contributions. The HR Payroll project had an increase in costs of $3.9 million and the MAK project had an increase in costs of $2.2 million. CBS reports that the timing of expenditures on these projects is not linear and comparable from year to year. Instead, the expenditure patterns are related to the various phases of the projects from planning to implementation and post go-live support. Essentially, the costs of the projects cannot be expected to be distributed equally from year to year due to different levels of activity in each phase. This suggests that while costs vary, the differences in cost over time should be known and planned for.

However, the MAK project is significantly under budget. Operating expenditures are $1.4 million below budget (42% variance) and capital expenditures are $1.9 million below budget (55% variance). The main variance in operating expenditures is in Purchased Services. CBS notes that the variance is explained by lower than planned professional fees as some consultants joined the project at a later time than expected and the delay in the purchase of MAK web based training systems. On the capital side there was a delay in the purchase of hardware. CBS reports that this variance is due to timing of spending and approximately $2 million in computer equipment was ordered in the first quarter of 2002/2003. These observations raise concerns about the pace of progress on this project, particularly since planning for MAK began in 1998.

The remaining $2.6 million increase in costs, according to CBS, has been attributed to the change in activity, as additional projects are initiated and others are completed. The provision of more detailed information on project costs and the timing of these costs is an area of improvement for CBS.

Exhibit 3-21: Breakdown of Other Blood Operations Costs

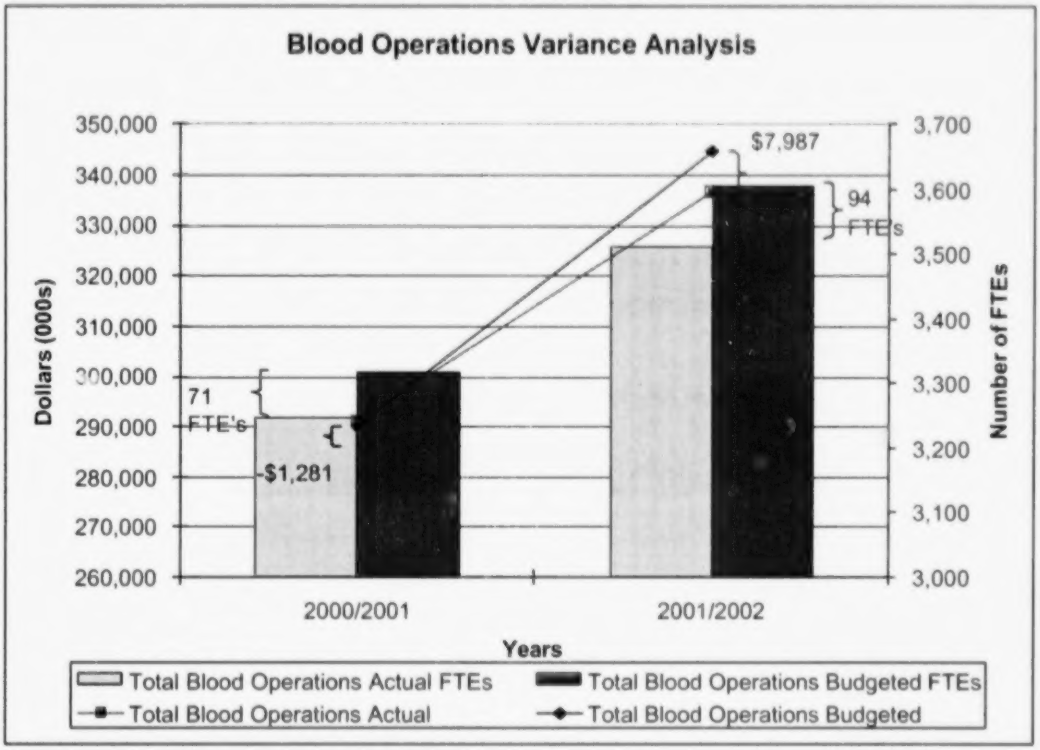
Actual 2000-2001 Vs 2001-2002
Line 84 Other Costs

	2001-2002	2000-2001	Inc.(Decrease)	% Incr/Decr
Projects				
Lookback/Traceback	3,550,994	2,124,552	1,426,442	67%
vCJD	154,876	77,873	77,003	99%
SAP Inventory	268,507	-	268,507	26850700%
HR pay project	6,879,821	2,941,984	3,937,837	134%
MAK	3,562,704	1,365,310	2,197,394	161%
Service Delivery model	245,331	-	245,331	24533100%
Transformation	877,520	2,732,808	(1,855,288)	-68%
National Product	38,839	-	38,839	3883900%
Consolidated testing	141,678	-	141,678	14167800%
National Contact Centre	640,276	-	640,276	64027600%
Store Samples Testing	3,624,966	2,349,767	1,275,199	54%
NAT	2,805,024	1,007,555	1,797,469	178%
Leukoreduction	83,971	(175,602)	259,573	-148%
Emergency Response	230,813	-	230,813	23081300%
IGIV conference	20,000	-	20,000	2000000%
Compensation and Retention	-	116,473	(116,473)	-100%
Y2K	-	49,747	(49,747)	-100%
Legal	-	554,005	(554,005)	-100%
Building & Equipment	587,741	454,759	132,982	29%
SAP	-	385,877	(385,877)	-100%
HO Restricted fund	-	519,011	(519,011)	-100%
Unallocated Corp. Expense	26,631	367,672	(341,041)	-93%
Misc expense -Blood Imports Cos	-	99,875	(99,875)	-100%
Total Costs	**$23,739,692**	**$ 14,971,666**	**$ 8,768,026**	**59%**

It was beyond the scope of this study to do a detailed review of each of the 23 projects listed above. Collectively, the costs are significant and some of the individual projects are substantial (e.g. HR Pay, MAK, Stored Samples, etc.). Some of these projects are CBS funded through Member Contributions and others are funded with transition funds. Members need to ensure that they are requesting and receiving detailed information on the financing and status of these projects.

3.2.1.10 Blood Operations Comparison of Budgets and Actual Expenditures

Exhibit 3-22: Blood Operations Variance Analysis



Please note that Blood Operations in this section includes expenditures for Patient Services. As Patient Services is a small component, this should not affect the overall costs significantly.

	2001/02 ($000s)				2000/01 ($000s)		
	Actual	Budget	Difference		Actual	Budget	Difference
Total Blood Operations Expenses	336,577	344,564	7,987		291,269	289,988	(1,281)
Total Blood Operations FTE's	3,512	3,606	94		3,247	3,318	71

There has been little variance between the budget and actual results for Blood Operations. The graph above shows that CBS came in below their budget by $7.9 million for fiscal 2002 in both expenditures and FTEs. They were slightly over budget in fiscal 2001 by $1.3 million. These figures have been updated to reflect final audited values.

The $7.9 million does not necessarily appear as a surplus on the Statement of Operations. Collectively five projects that are funded by deferred monies have a favourable variance of $5.1 million. In accordance with the deferral method of accounting, revenues are recognized based on actual expenses. Therefore the favourable variance does not result in a surplus. In addition to this $5.1 million there is $0.7 million, which appears as a surplus in the financial statements.

A review of budget statements for the Centres found that 13 out of 14 Blood Centres and both plasma centres were over budget in the last fiscal year. This suggests that there is a systemic problem and a need for improvement in Centre demand forecasting and/or improvement in fiscal management. This is a concern because the Centres represent the core business of the organization. As such, they should be appropriately resourced then soundly managed within their resource allocation. In the last year, budget deficits in the Centres were offset primarily by budget surpluses in projects. Centres are also working hard to increase efficiencies and this may account for some of the under expenditures (e.g., collections) but the issue requires investigation.

Recommendation #29: The existence of budget deficits at all Blood Centres except one is a concern that should be addressed. It is recommended that CBS re-examine the resourcing of the Centres relative to the overall budget approved by the Members to ensure that the core business is adequately resourced. CBS should assess the need for education and support for Centre Directors and staff in the areas of demand forecasting, budget development and budget management.

3.3 Patient Services

In 2001/02, Patient Services accounted for $11.3 million, or one percent, of the total CBS Budget. Patient Services includes a range of tests performed for hospital patients rather than blood donors. Some of the tests are very specialized. Patient Services is theoretically funded separately but in practice it is treated as part of Blood Operations.

Each patient service is priced according to a fee schedule. Throughout the budget process, an estimate of the number of procedures that will take place for that particular service is forecast and a budget for Patient Services is set. The fee schedule for patient services includes the following cost items:

1. Direct Labour Costs
2. Medical Supplies
3. Administrative Costs

Costs that are not captured in the fee schedule include:

1. Capital Costs
2. Indirect overhead costs such as:
    a. Administrative support in the centres
    b. Facility charges
    c. Finance and IT support from Head Office

Since all costs for patient services are not fully recoverable, patient services is effectively being subsidized to some extent by Blood Operations. This should be addressed in the future to provide an accurate estimate of the cost of delivering patient services.

Recommendation #30: It is recommended that CBS develop and implement a cost recovery model for all Patient Services pending the outcome of the current project that will determine which Patient Services are to be maintained.

3.4 Fractionated Products

3.4.1 Fractionated Products Overview

Fractionated products include a range of products derived from the various proteins found in plasma. The process of fractionation isolates and extracts specific proteins from pools of plasma. There are also some fractionated products that can be manufactured and are not derived from human plasma. These are called "recombinant" products. There has been a high demand for recombinant products because of the perception that they are safer than plasma-derived products.

Canada does not have a fractionation plant. Therefore, most fractionated products are purchased from American suppliers. The supplier ships the product from the U.S. to the CBS fractionated product warehouse in Ottawa. The warehouse then ships the products to each of the 14 Centres. The Centres ship the products to the hospitals along with their order of blood components.

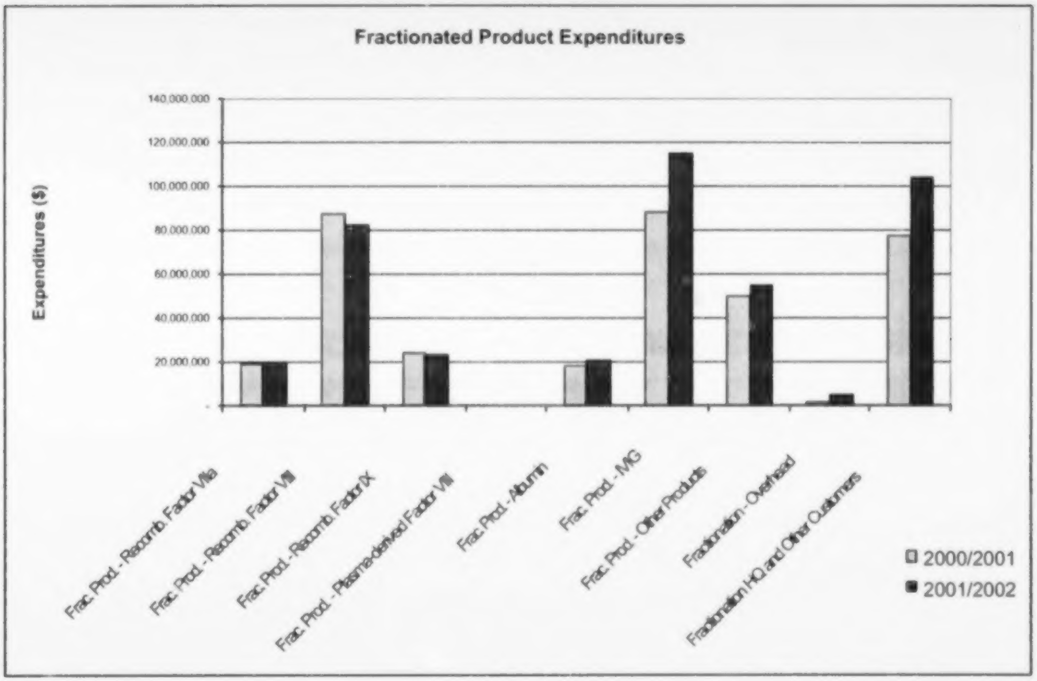
CBS purchases Fractionated Products for Hema-Quebec and other customers. These costs are fully recoverable. In 2001//02, $1.1 million was recouped from Hema-Quebec to offset infrastructure, overhead and administrative costs associated with managing the Fractionated Product Program.

In 2001/02, CBS expenditures on Fractionated Products were $313 million. This represents an increase of 11% or $31.5 million over the previous year. This is a fairly large increase and in order to understand the factors behind it a detailed analysis is provided below.

Exhibit 3-23: Breakdown of Fractionated Products Expenditures

	2002	2001	Change	Change
Frac. Prod. - Recomb. Factor VIIa	20,236,348	19,539,360	696,988	4%
Frac. Prod. - Recomb. Factor VIII	82,093,422	87,384,679	-5,291,257	-6%
Frac. Prod. - Recomb. Factor IX	23,256,144	24,211,242	-955,098	-4%
Frac. Prod. - Plasma-derived Factor VIII	178,752	0	178,751	17875100%
Frac. Prod. – Albumin/Pentaspan	20,781,281	18,400,717	2,380,564	15%
Frac. Prod. - IVIG	114,863,170	88,201,235	26,661,935	30%
Frac. Prod. - Other Products and Costs	55,082,592	49,965,844	5,116,748	10%
Fractionation - Overhead	5,198,654	1,640,445	3,558,209	217%
Fractionation HQ and Other Customers	103,702,025	77,503,220	26,198,805	34%
Total Fractionated Products	**416,389,003**	**358,703,507**	**57,685,496**	**16%**
Total Fractionated Products without HQ and Other Customers	**312,686,978**	**281,200,287**	**31,486,691**	**11%**

Exhibit 3-24: Fractionated Product Costs by Product or Functional Area



The table and graph above show that the largest increases were for IVIG, Other Products and Overhead. The total CBS expenditures for "other products" includes $5,603,671 in "overhead recovery and adjustments" for 2001/02.

3.4.2 Fractionated Product Cost Drivers

There are three main cost drivers of Fractionated Products:

USD$/CDN$ Foreign Exchange Rate
Greater then 90% of the Fractionated Products purchased are purchased in US dollars. This means that costs vary depending on the foreign exchange rate. This is not something that CBS can control.

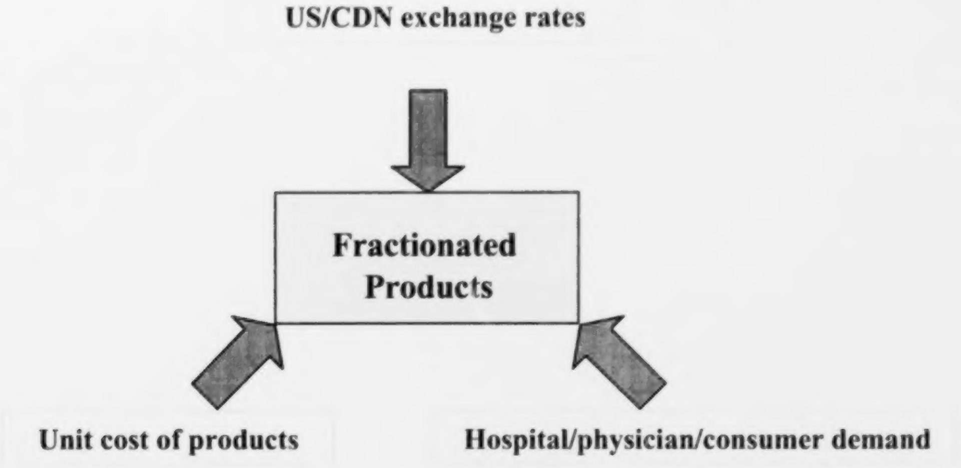
Cost per Unit of Fractionated Products
Globally, the fractionated product industry is very volatile and subject to fluctuations in the availability of products. In the last couple of years, there have been shortages of high use products that have contributed to unit cost increases. As later analysis will show, the cost of fractionated products has been increasing beyond inflation and in some instances such as IVIG, the costs have been increasing at a very significant rate.

Demand of Fractionated Products

The demand for fractionated products has been increasing due to physician practice patterns and product preferences. Health care policy also plays a role. For example, in Canada, fractionated products are used for prophylactic treatment of hemophiliacs as well as for therapeutic purposes. In some other countries, there are more restrictive polices on the use of fractionated products for hemophilia. Many consumers are very knowledgeable about the different types of fractionated products available. Some consumer groups (e.g. hemophiliacs) will use these products on a regular basis for their entire lives. Consumer preferences also appear to be contributing to the rising demand for certain products as they make their wishes known to physicians (and to CBS).

The diagram below summarizes the key cost drivers for Fractionated Products.

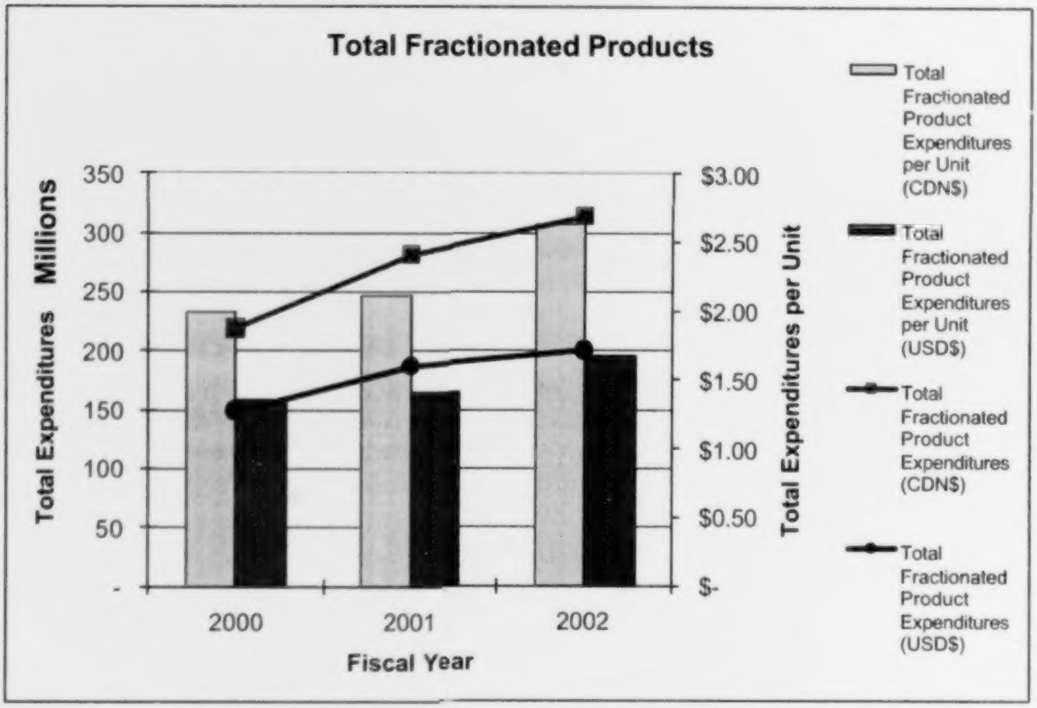
Exhibit 3-25: Fractionated Product Cost Drivers



The cost of Fractionated Products has increased dramatically over the past few years and this is portrayed in the following graphs which include a look at the trend for specific types of products.

The first diagram below shows that total fractionated expenditures have been increasing even when exchange rates are controlled for. The cost per unit of fractionated products is also increasing, as denoted by the bars.

Exhibit 3-26: Trends in Total Fractionated Products



By converting the total expenditures on Fractionated products from CDN$ to US$, it is apparent that the increase is not completely due to the CDN$/USD$ exchange rate. Regardless of whether the expenditures are expressed in CDN$ or US$, the trend is still increasing.

Over the three year period the CDN$/US$ exchange rate increased from 1.47 to 1.50 to 1.56. The cost per unit of fractionated products has also increased. This increase in global market prices is evident with and without the CDN$/USD$ exchange rate conversion factor.

Over the past three years there has been a dramatic increase in the demand for certain fractionated products. From 1999/00 to 2000/01, the number of equivalent units purchased rose by 22%. From 2000/01 to 2001/02 the number of equivalent units decreased by 10%.

However, the reduction in the number of units purchased was offset by price increases (particularly for certain high demand products where usage increased) and exchange rate increases.

On the following pages, this same analysis is performed on key individual products.

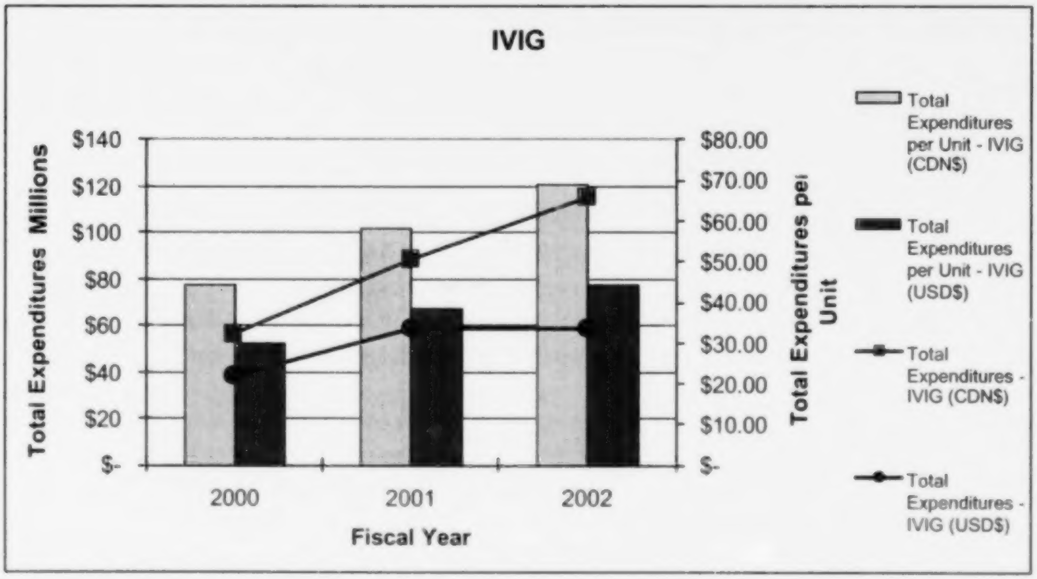
The information on the following pages addresses specific fractionated products. They highlight trends over time in:

- Cost per unit (i.e., price);
- Total expenditures (i.e. cost per unit multiplied by number of units purchased by CBS), expenditures reflect the value of the products shipped to hospitals in each province so "units purchased" and "units shipped" are used inter-changeably,
- Product usage.

IVIG

Intravenous Immune Globulin (IVIG) belongs to a group of products known as immunizing agents. IVIG is used to prevent or treat some illnesses that can occur when an individual has a compromised immune system. CBS spends more on IVIG than any other purchased item. Last year, total IVIG expenditures were $114,863,170. This represents 37% of total CBS fractionated product expenditures. The graph below highlights the dramatic increases in the unit cost of IVIG over the past three years. This can be attributed to decreased global supply of the product. Anecdotally, it has been suggested that increased demand due to physician practice patterns has also contributed to the rise in IVIG expenditures.

Exhibit 3-27: Trends in IVIG



In 2001/02, CBS purchased 11 different IVIG products. For seven of these products, the number of equivalent units experienced an increase from 2000/01 to 2001/02. The percentage increase in units shipped to hospitals ranged from 39% to 80% depending on the product.

Four products experienced a reduction in the units shipped ranging from a 19% decrease to a 50% decrease.

The data below shows that, overall for IVIG, while volumes have certainly increased, costs are the dominant factor.

Exhibit 3-28: Changes in IVIG Usage and Expenditures

	1999/00	2000/01	2001/02
IVIG Units Purchased	1,264,783	1,522,099	1,665,357
% Change in Units Purchased	–	20%	9%
IVIG Expenditures	$56,057,454	$88,201,235	$114,863,170
% Change in Expenditures	--	57%	30%

Increased utilization of IVIG is a global phenomenon. Data from the international benchmarking survey shows the increase in the number of units of IVIG distributed from 2000/01 to 2001/02 for four blood service agencies. Each blood service may define a "unit" differently however valid comparisons can be made of the percentage change over time.

Exhibit 3-29: Increases in IVIG Utilization in Other Jurisdictions

Blood Service Agency	Percent Increase in IVIG Units from 2000/01 to 2001/02
CBS	9%
Hema-Quebec	5%
United Kingdom	22%
American Red Cross	45%

International data compiled by CBS found that, compared to six other countries, CBS had the highest IVIG utilization per capita based on estimates for the year 2000[27]. The results were as follows:

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[27] "International Comparative Review of Blood Systems", Presented to CBS Corporate Members November 2001.

Exhibit 3-30: International Comparison of IVIG Utilization per Capita

Country	IVIG Utilization per Capita (grams/1,000 population)
CBS	67.0
United States	62.5
Germany	42.5
New Zealand	36.3
Sweden	32.0
Australia	27.5
Japan	27.5

CBS' assessment of these results concluded that "these differences are likely due to differences in clinical practices". These results support the view that there are opportunities to reduce IVIG utilization (and associated costs) through utilization management approaches that impact clinical practice.

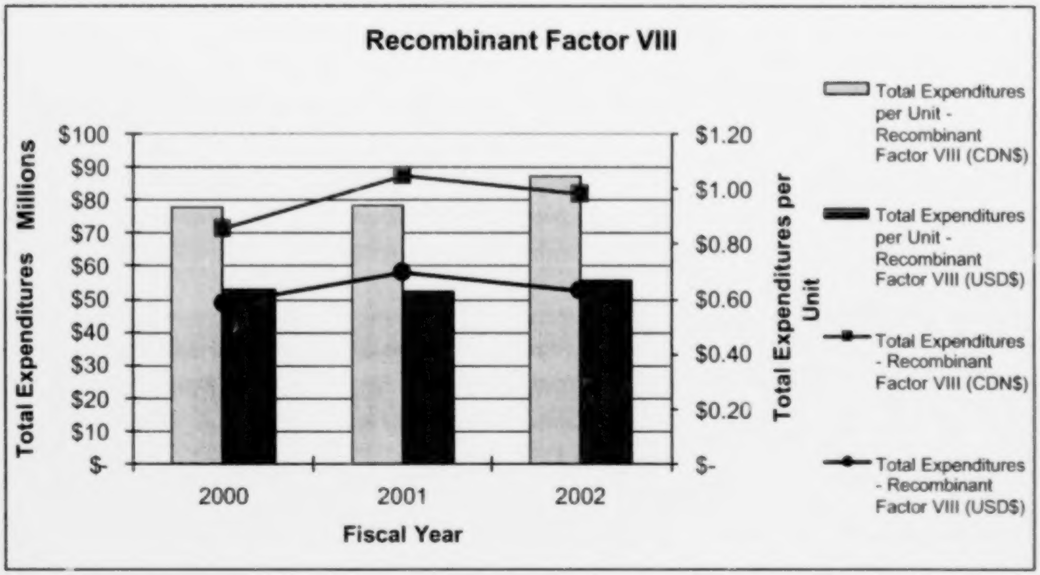
Later in this report, data will be presented that shows that not all IVIG usage is approved usage. In summary, all three cost drivers (exchange rate, increased demand and increased unit pricing) contribute to IVIG expenditure increases.

Recombinant Factor VIII

Antihemophilic factor or Factor VIII, can be manufactured from human blood or through recombinant means. Although originally used for haemophilia, von Willebrand's disease, and disseminated intravascular coagulation, it is also used as a source of fibrinogen in cardiothoracic surgery and obstetric emergencies. The preferred therapy for haemophilia and von Willebrand's disease now includes recombinant factor concentrates.

In the last fiscal year, CBS spent $82,093,422 on Recombinant Factor VIII. Overall expenditures on Recombinant Factor VIII have decreased in the past year. This is attributed to a global shortage of the product. It is important to emphasize that this downward trend is considered an anomaly and it is expected that the expenditures on Recombinant Factor VIII will increase next year now that product supply has stabilized. The graph below shows that unit cost (i.e. price) of the product has increased over the past three years. Part of this is due to exchange rate factors because the price increases are not as large when the price is expressed in US dollars.

Exhibit 3-31: Trends in Total Recombinant Factor VIII



In 2001/02, CBS purchased significant volumes of six Recombinant Factor VIII products for shipment to hospitals. For four of these products, more units were shipped in 2001/02 than in the previous year. The amount of the increase ranged from 7% to 101% depending on the product. One product was not purchased in previous years and one product experienced a 69% drop in the number of units shipped.

The overall change in the equivalent units purchased/shipped and total expenditures is shown below:

Exhibit 3-32: Changes in Recombinant Factor VIII Usage and Expenditures

	1999/00	2000/01	2001/02
Rec. Factor VIII Units Purchased	76,422,594	92,625,923	78,192,213
% Change in Units Purchased	--	21%	-16%
Rec. Factor VIII Expenditures	$71,319,886	$87,384,679	$82,093,422
% Change in Expenditures	--	23%	-5%

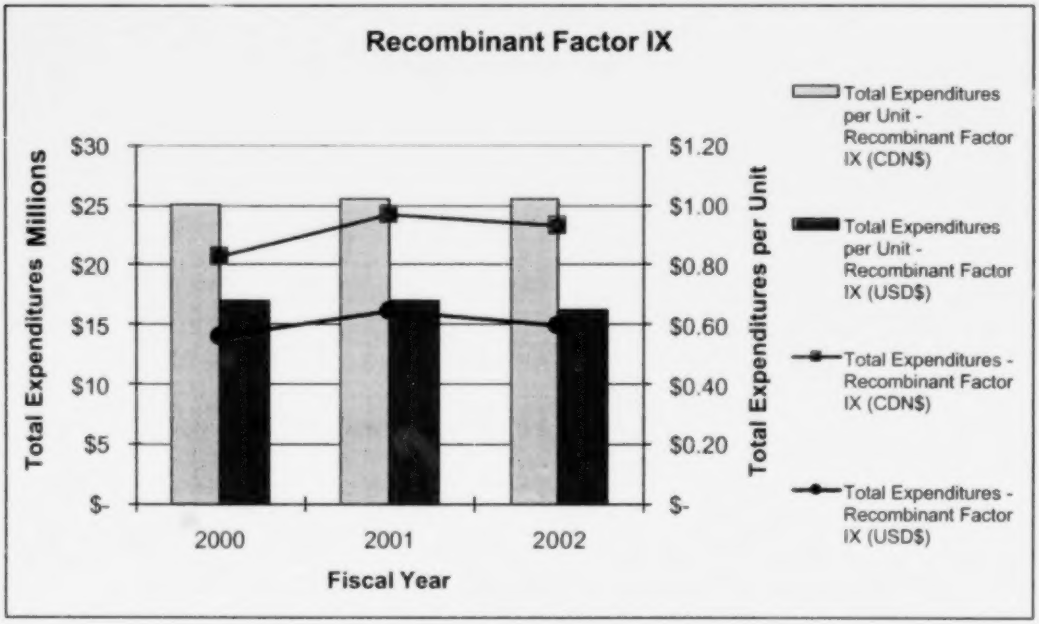
The data shows that expenditures have grown at a slightly higher rate than the volume of units purchased, suggesting that costs are the dominant factor.

Recombinant Factor IX

Factor IX is another key protein in the blood clotting process. Injections of factor IX are used to treat Haemophilia B, (sometimes called Christmas disease). Injections of Factor IX complex may also be used in patients in whom the medicine used to treat Haemophilia A is no longer effective.

Last year, CBS expenditures on Recombinant Factor IX totalled $23, 256,144. The graph below shows that expenditures on Recombinant Factor IX increased from 1999/00 to 2000/01. This was followed by a slight decrease from 2000/01 to 2001/02. This appears to be due to a decrease in the unit cost of the product as evidenced by the downward trend when cost per unit is expressed in US dollars.

Exhibit 3-33: Trends in Recombinant Factor IX



For the past three years, CBS has purchased five different Recombinant Factor IX products. In the past year, the number of equivalent units purchased increased for three of the products. The increases ranged from 55% to 113%. One product experienced virtually no change in volume and another product experienced a 49% drop in volume.

The overall change in the equivalent units purchased and total expenditures is shown below. For this product, the volume and cost changes were fairly consistent.

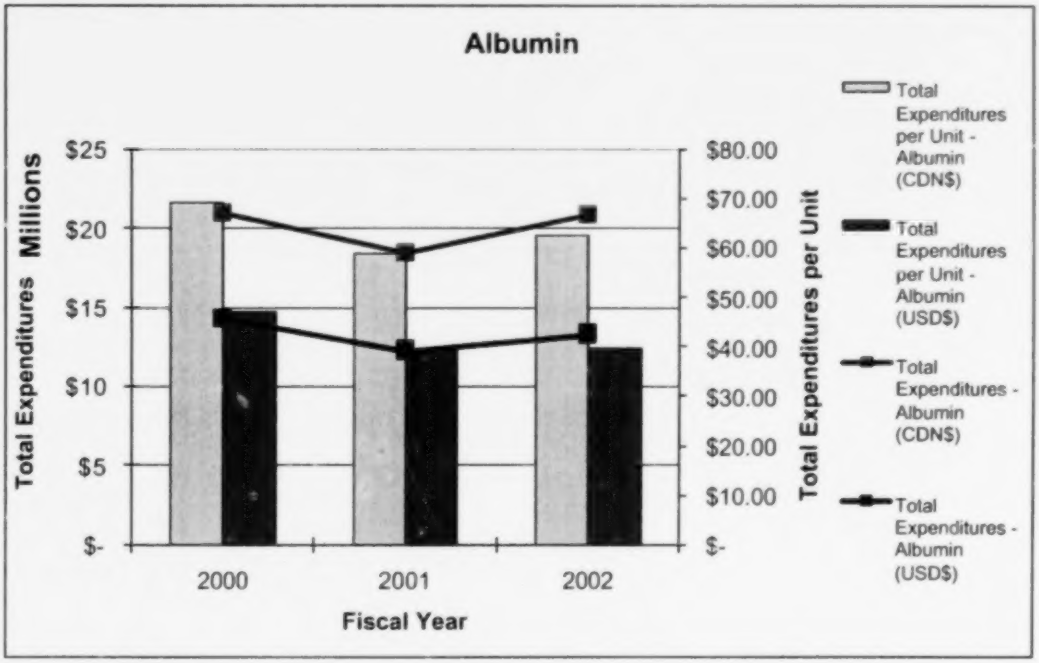
Exhibit 3-34: Changes in Factor IX Usage and Expenditures

	1999/00	2000/01	2001/02
Rec. Factor IX Units Purchassed	20,551,752	23,657,330	22,790,485
% Change in Units Purchased	--	15%	-4%
Rec. Factor IX Expenditures	$20,637,203	$24,211,242	$23,256,144
% Change in Expenditures	--	17%	-4%

Albumin/Pentaspan

Albumin is a protein found in plasma. The main role of albumin is two fold: 1) as a transporter of small molecules in the blood (such as bilirubin, calcium, some hormones, and drugs) and 2) to prevent blood from leaking out into the tissues. Last year, CBS spent $20,781,281 on Albumin products. This includes $9,003,385 on Pentaspan. The cost per unit of Albumin decreased slightly from 1999/00 to 2000/01 and increased the following year. Total expenditures followed the same trend.

Exhibit 3-35: Trends in Albumin



In 2001/02, CBS purchased nine different Albumin products and two different Pentaspan products. Five of the products were purchased in greater volume than in the previous year. The increase in the equivalent units purchased for these products ranged from 3% to 93%. Three products experienced a substantial drop in units purchased. The remaining three products were not purchased in previous years.

The overall change in the equivalent units purchased/shipped and total expenditures is shown below:

Exhibit 3-36: Changes in Albumin/Pentaspan Usage and Expenditures

	1999/00	2000/01	2001/02
Albumin Units Purchased	302,628	311,835	332,870
% Change in Units Purchased	--	3%	7%
Albumin Expenditures	$20,971,276	$18,400,717	$20,781,281
$ Change in Expenditures	--	-12%	13%

Recombinant Factor VIIA

Factor VIIa is a man-made protein produced to replicate the naturally occurring activated Factor VII (factor VIIa) in the body. Factor VIIa is used to stop bleeding of injuries for patients with haemophilia by helping the blood to clot. This man-made protein, Factor VIIa, is used in people who have Haemophilia A (a deficiency of clotting Factor VIII) or Haemophilia B (a deficiency of clotting Factor IX) who have also formed antibodies against other clotting proteins that help bleeding to stop.

Last year, CBS expenditures on Recombinant Factor VIIA totalled $20,236,348. Expenditures on this product have been increasing. This product is purchased from a Canadian supplier with payments made in Canadian dollars so the exchange rate is not an issue. From 2000/01 to 2001/02, the price per unit increased from $900 to $917.30.

Three different types of Recombinant Factor VIIA have been purchased by CBS each year for the past three years. From 1999/00 to 2000/01, all of the products experienced an increase in units ranging from 17% to 116%. The following year there was a slight drop in the units purchased for two of the products while the third product experienced a 40% increase in units.

The overall change in the equivalent units purchased/shipped and total expenditures is shown below:

Exhibit 3-37: Changes in Recombinant Factor ViiA Usage and Expenditures

	1999/00	2000/01	2001/02
Rec. Factor VIIa Units Purchased	11,902	21,600	22,061
% Change in Units Purchased	--	81%	2%
Rec. Factor VIIa Expenditures	$11,284,850	$19,440,000	$20,936,348
$ Change in Expenditures	--	-72%	8%

Other Fractionated Products

Several other fractionated products accounted for a combined total of $46,257,990 in expenditures last year. The major contributors to this expenditure were Synagis and WinRho, with expenditures of approximately $16 million and $4 million respectively..

Fractionated Product Overhead

Overhead costs account for $5.2 million or approximately 1.6% of total fractionated costs. This is an important area for analysis because it is one of the few components of the Fractionated Products program that CBS can control. Overhead increased by 217% or $3.6 million from 2000/01 to 2001/02. This is a significant increase that appears to be due largely to a change in allocation of costs. The table below shows that the increase can be attributed to two main areas: Administrative Services and Labour Costs.

According to CBS, the substantial variance in Administrative Service cost was the result of a "Write-off Provision" and "Write-off Recovery". The inventory write-off reserve had increased by $1.1 million due to shipment problems related to temperature controls while in transit within Canada. Write-off of Monoclate contributed an additional $1.3 million to the variance. Due to increased demand and activity, freight and courier costs increased by $261,500. In total, this resulted in a $2.8 million variance from 2000/01 to 2001/02.

Labour costs increased by $428,038 due primarily to staff costs reallocation from Administration/Overhead at the National Level to the Fractionation Program ($305,000), which includes direct staff support such as the Director of Plasma Procurement, Warehouse Inventory Clerk and financial analysts.

Exhibit 3-38: Breakdown of Fractionation Program Overhead

Fractionation Program - Overhead	**2001-2002**	**2000-2001**	**Change**	**% Change**
Labour Costs	1,032,402	604,364	428,038	71%
Medical Supplies	-	-	-	
Travel	84,991	43,441	41,550	96%
Admin. Services	4,286,992	1,539,172	2,747,820	179%
Professional Fees	304,588	285,050	19,538	7%
Other Purchased Services	117,481	178,068	(60,587)	-34%
Property Expenses	-	96	(96)	-100%
Equipment	1,598	2,108	(510)	-24%
Misc expense - Costs Recovery	(630,020)	(1,011,854)	381,834	-38%
Total Costs	**$5,198,032**	**$1,640,445**	**$ 3,557,587**	**217%**

Recommendation #31: While there are some aspects of the Fractionated Products function that are outside of the control of CBS, it is recommended that CBS find innovative ways to manage fractionation cost increases. Consideration should be given to both strategies that increase supply in a cost-effective manner and strategies that reduce demand. For example:

- To increase the supply, CBS should make a decision about plasma self-sufficiency. The MOU identifies self-sufficiency in plasma collections as something that should be encouraged. The decision should me made in the context of a policy forum involving CBS, Members, Health Canada and the public. If plasma self-sufficiency is confirmed as a goal, various options for plasma self-sufficiency should be developed and analyzed from a cost-benefit-risk perspective.
- To reduce the demand, CBS should:
  - Develop national utilization guidelines for key blood components and products. This should be done in conjunction with the National Technical Working Group. Priority should be given to the development of guidelines for the use of fractionated products, particularly IVIG and Factor VIII because of their rapidly rising costs. Future consideration should be given to guidelines for high cost blood components such as platelets with a view to maximizing appropriate use and minimizing unnecessary discards. The Provincial/Territorial Ministers of Health will then need to decide whether to mandate the use of these guidelines in their health care systems as part of their provincial/territorial utilization management process. Ideally, these guidelines should be supported on a national basis
  - Disseminate the results of the IVIG Consensus Conference held in October 2000.

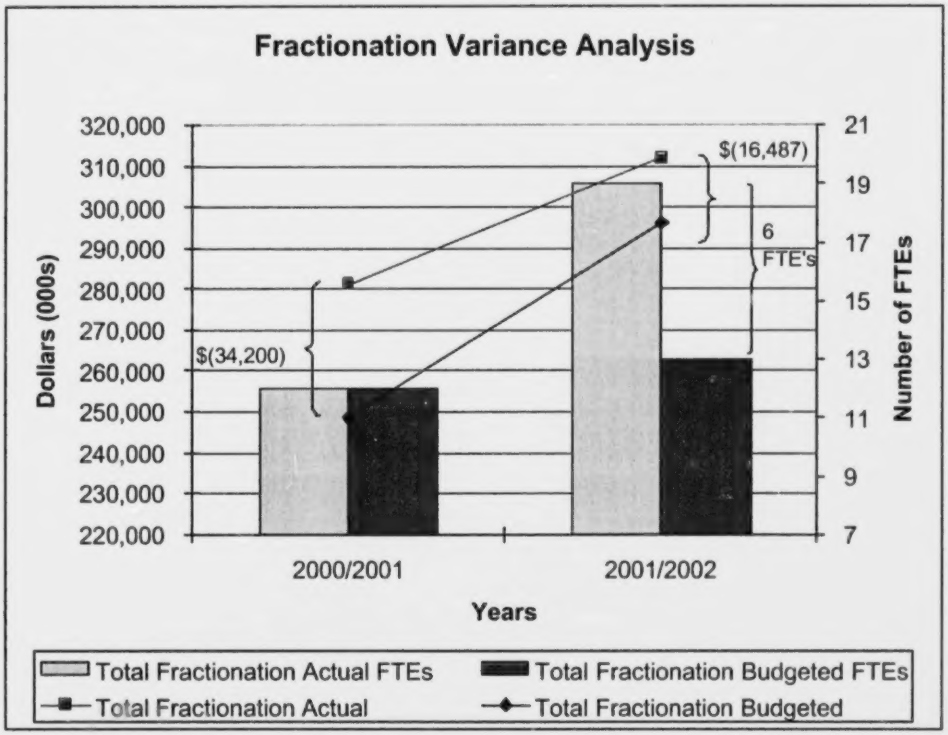
- Explore a comprehensive range of utilization management options along a spectrum from guidelines to mandatory national standards to capping the fractionation budget for the provinces to charge back to hospitals (an option being explored by Hema-Quebec). The pros and cons of each option should be analyzed from a cost-benefit-risk perspective. For example, while capping the fractionation budget would limit costs, the risks would include public outcry from the hemophilia community and the possibility that hemophiliacs may not have access to the products they need once the budget cap is reached.

Recommendation #32: It is recommended that CBS identify ways to harvest the learnings from various provincial blood reference groups and hospital utilization committees that exist across the country. Specific suggestions might include an annual national forum (or series of regional forums) to share information from these various groups. The BC model for IVIG utilization management should be considered carefully for application to other provinces.

Recommendation #33: It is recommended that CBS consider using an expert advisory group, including physicians who use fractionated products and can provide information on clinical practice issues, to provide advice on the budget for fractionated products. The National Technical Working Group should also be considered a resource in this area.

3.4.2.1 Fractionated Products Comparison of Actuals, Forecasts and Budgets

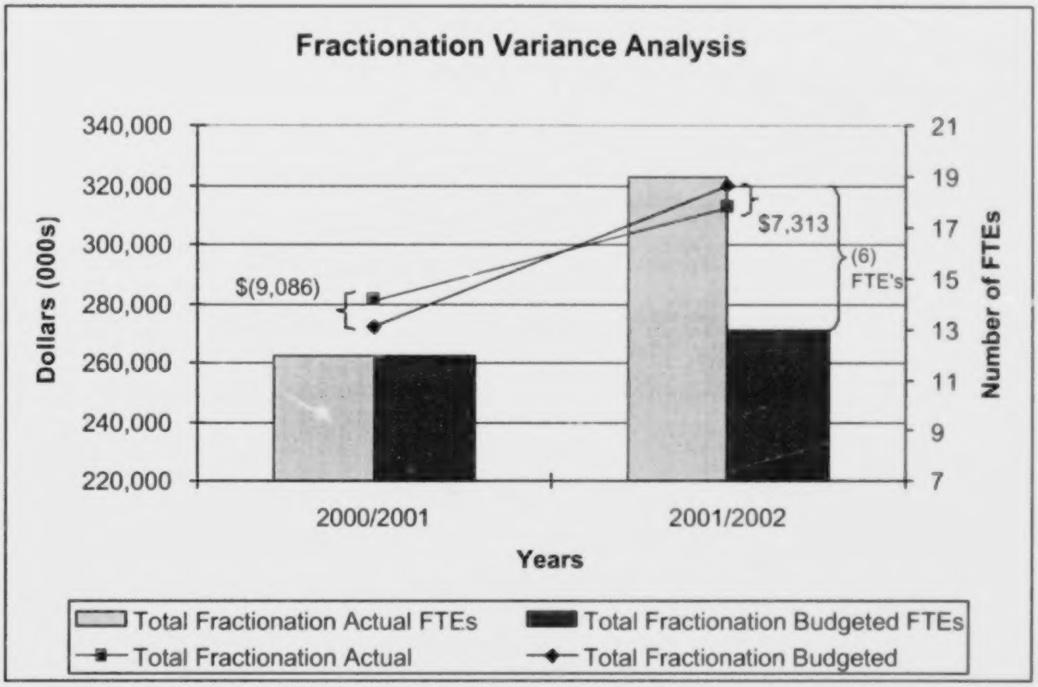
Exhibit 3-39: Actual Fractionated Expenditures versus Approved Fractionated Budget



	2002			2001		
	Actual	Budget	Difference	Actual	Budget	Difference
Total Fractionation Expenses	**312,687**	**296,200**	(16,487)	**281,200**	**247,000**	(34,200)
Total Fractionation FTEs	19	13 -	6	12	12	-

When comparing the actual expenditures to the budget that was approved by the provinces and territories, the variance is $16.5 million in fiscal 2002 and $34.2 Million in fiscal 2001.

Exhibit 3-40: Actual Fractionated Expenditures versus Original CBS Projected Fractionated Forecast



	2002			2001		
	Actual	Forecast	Difference	Actual	Forecast	Difference
Total Fractionation Expenses	**312,687**	**320,000**	7,313	**281,200**	**272,114**	(9,086)
Total Fractionation FTEs	19	13	(6)	12	12	-

This analysis demonstrates that the CBS estimates of fractionation expenditures are a relatively good predictor of actual fractionation expenditures. Original CBS forecasts come within less than $10 million (approximately 3%) of actual expenditures. However, due to funding constraints, the provinces and territories typically approve a budget that is less than the CBS forecast resulting in budget overruns. The variances between the Member approved budget and the actual expenditures is much greater than the variance between the CBS forecast and the actual expenditures. These results underscore the importance of the provinces/territories and CBS working collaboratively to set realistic and evidence-based budget goals.

3.5 Unrelated Bone Marrow Donor Registry (UBMDR)

UBMDR revenues are obtained by charging other blood organizations for performing donor searches. UBMDR expenses are all of the expenses incurred for managing the registry. This includes all labour, medical supply and other costs.

Under the current funding model, any variance between the revenue and the expenses must be funded from Blood Operations.

The UBMDR fee schedule is a reciprocal list of costs for providing UBMDR searches that has been agreed upon by blood organizations in Canada, the United States as well as internationally.

The graph below indicates that UBMDR expenses have been steadily increasing over the past few years. Based on this trend alone a continued increase into 2002/03 would be projected. However, this trend may be offset (in whole or in part) by the impact of a new bone marrow registry system that was implemented in June 2002. The new system is expected to reduce the effort and costs of the search process.

CBS has initiated a UBMDR Audit to understand and match their costs against the sources of revenue. They are currently in Phase I of the audit and are working towards allocating costs in the most appropriate manner as well as providing a detailed price analysis.

Exhibit 3-41: Unrelated Bone Marrow Donor Registry Revenues vs Expenses

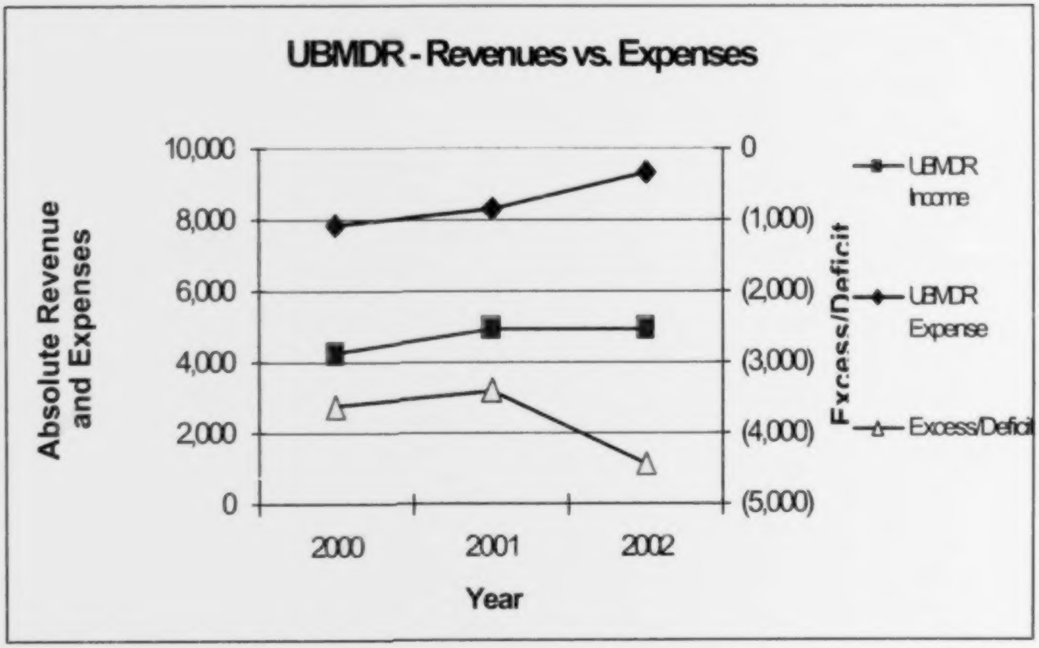
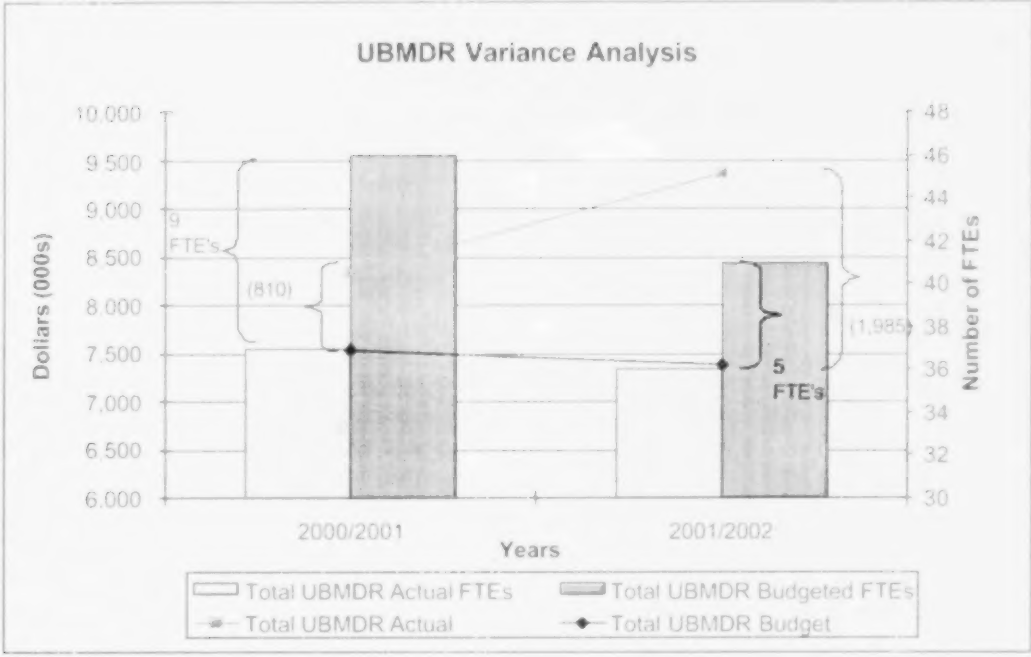


Exhibit 3-42: Unrelated Bone Marrow Donor Registry Variance Analysis

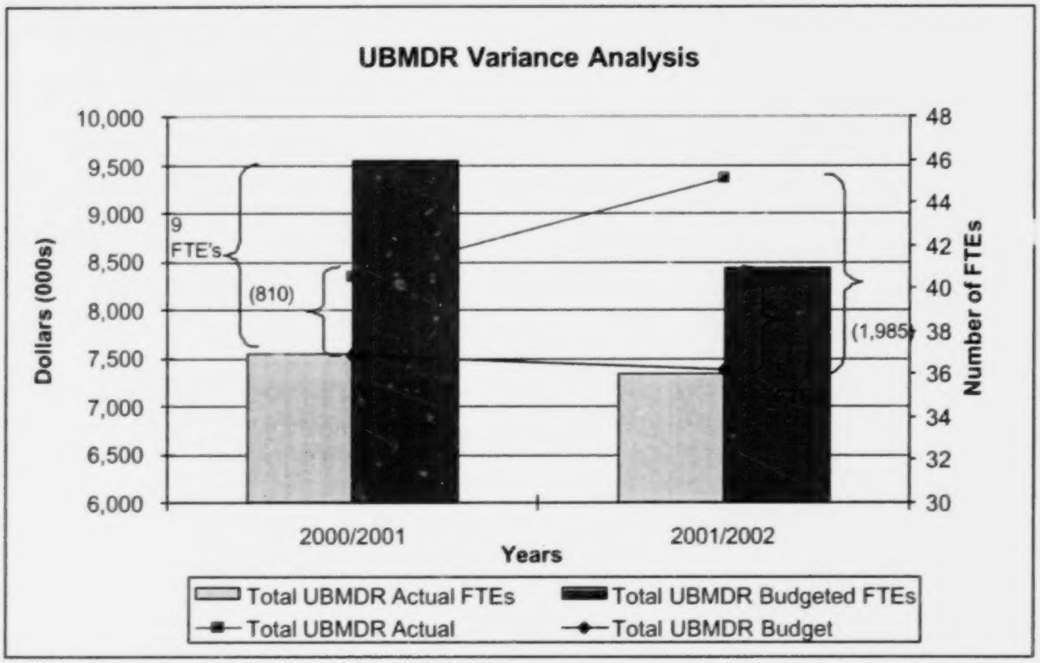


	2002				2001		
	Actual	**Budget**	**Difference**		**Actual**	**Budget**	**Difference**
Total UBMDR Expenses	**9,369**	**7,384**	(1,985)		**8,348**	**7,538**	(810)
Total UBMDR FTE's	36	41	5		37	46	9

There is a negative variance in UBMDR actual vs budget for fiscal 2002 and fiscal 2001. However, there is a positive variance in FTEs. According to the March 31, 2002 CBS Management Report, the UBMDR budget variance includes the following three components: 1) a favourable variance in operating expenses, 2) a favourable variance in Search and Transplant Fees and 3) an unfavourable variance in Search and Transplant Costs.

Recommendation #34: In order to fully understand the implications of the use of Unrelated Bone Marrow Donor Registry (UBMDR), it is recommended that the current system of funding be re-evaluated as UBMDR has different cost drivers than Blood Operations. The full cost implications of the UBMDR program is not well understood, as the revenues generated from donor searches may not necessarily match the expenses incurred from completing those searches. Under the current system, all UBMDR expenses are accumulated and expensed as part of Blood Operations and all revenues received from donor searches are incorporated into the Blood Operations. As well, it is unclear whether or not all UBMDR search costs are fully accounted for, as there are

Exhibit 3-42: Unrelated Bone Marrow Donor Registry Variance Analysis



	2002				2001		
	Actual	**Budget**	**Difference**		**Actual**	**Budget**	**Difference**
Total UBMDR Expenses	**9,369**	**7,384**	(1,985)		**8,348**	**7,538**	(810)
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3.6 International Cost Comparators

3.6.1 Methodology and Limitations

The previous sections in this chapter examined CBS service costs in detail and compared expenditure levels over time. In this section, an attempt is made to compare CBS expenditures with expenditure levels in other countries. Most of the information gathered in this section was obtained through an international benchmarking survey that was sent to a number of other blood agencies in June 2002. Responses were received from Hema-Quebec, Sweden, the United Kingdom (England and North Wales), the American Cross and, of course CBS.[28]

The goal of the international benchmarking exercise, as set out in the terms of reference for the review, was to collect financial and operational performance "indicators". The definition of an indicator is important in framing expectations about the results of the benchmarking survey. An indicator is a screen or flag that is used to monitor quality. Indicators provide a high level overview of performance levels; they point you in the right direction but do not provide an understanding of why performance is at a specified level or what needs to be done to improve performance.[29]The purpose of this section is to highlight similarities and differences between CBS costs and the costs reported in the comparator countries. No attempt is made to explain the cost variations since that would require a detailed understanding of the regulations, policies, procedures and resources in place in each of the comparator countries. Identifying differences will hopefully provide an opportunity for CBS and/or provincial/territorial governments to contact the comparator countries to explore cost reduction strategies.

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[28] Some financial data was also obtained informally from five American blood centres (non-Red Cross) that submitted cost data in aggregate format for the five centres. Unfortunately, the most recent year provided was 2000 which made it impossible to make valid comparisons with the other respondents that provided data for 2002 and 2001.

[29] Canadian Institute for Health Information

It is important to note, that the international benchmarking survey gathered a broader range of performance indicators than what is presented in this section. Other indicators have been integrated into the sections of the report where they are most relevant.

Also, with the exception of CBS and Hema-Quebec, other countries did not complete the entire survey questionnaire. Questions requiring detailed financial data had the poorest response rates. Data about fractionation costs was usually not provided. Some countries could not provide a breakdown of costs by functional area and cost category (i.e. labour, medical supplies, other). Some countries could not provide detailed financial data for two fiscal years. The questions that were more likely to be answered were:

- Descriptive questions about the nature of the blood system (e.g. population size, functions provided, tests conducted, hospital charges, etc.)
- Donation statistics
- Volume of blood collections
- Labour hours (at least at the high level)

Comparing the financial indicators of different blood organizations around the world is a very difficult task as there are many variables to be considered. These variables include:

- Regulatory and Safety Requirements. Each blood organization has different regulatory requirements which may have an impact on the amount and type of labour and medical supplies that will be required for blood operations. Blood agencies also vary in terms of the types of tests that they perform on donor samples.
- Operating Policies. There will be variations in operational policies across countries. Differences might include things such as the age criteria for donors.
- Geographical Considerations. Distribution costs will vary depending on the size of the catchment area covered by the blood agency. None of the other blood agencies that responded to the survey cover a geographical area as large as CBS.
- Exchange Rates. Foreign exchange rates must be accounted for to establish a common currency for comparative purposes.
- Cost Allocation. Different blood organizations allocate their costs differently. For example, some organizations may account for plasma collection costs in their Fractionated Product Costs and some may include it in their Blood Operations. There might also be variations in what items are considered administrative overhead versus direct service costs. The international benchmarking survey sought to address this issue by providing very specific definitions of the cost indicators requested. However, there is no way of guaranteeing all respondents complied with these definitions.

The information presented below is for fiscal year 2002 and all costs have been converted to Canadian dollars. There has been no attempt to standardize costs to adjust for purchasing price parity. In the graphs, "US" refers to data obtained from the American Red Cross.

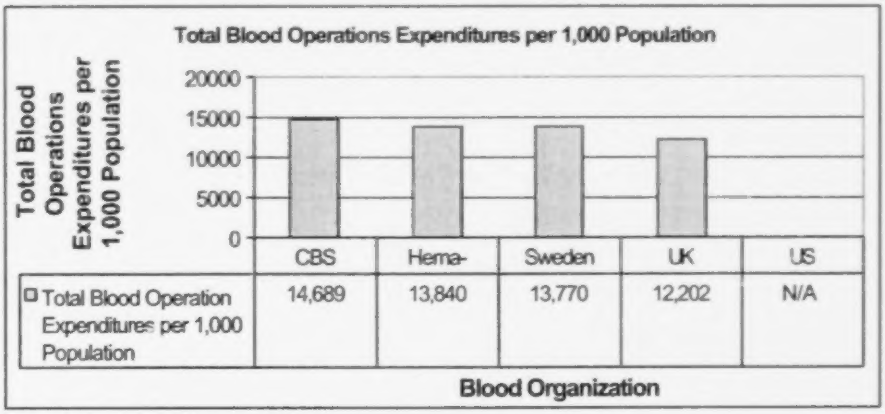
3.6.2 Blood Operations Cost Per Population

The purpose of this indicator is to compare the per capita investment that different countries/regions are making in their blood systems. This indicator should be of interest to funders of the blood system as they seek to determine what level of funding is safe, affordable and sustainable.

The data reported below is only for Blood Operations. Fractionated Product Costs and UBMDR costs have not been included because not all respondents provided this data.

CBS reported the highest Blood Operations Costs per 1,000 Population ($14,689 per 1,000 population), followed by Hema–Quebec ($13,840 per 1,000 population). CBS costs are 6% higher than Hema-Quebec costs. Then followed the two European countries. This result might be partially explained by the larger geographic catchment area covered by CBS.

Exhibit 3-43: International Comparison of Blood Operations Costs Per 1,000 Population



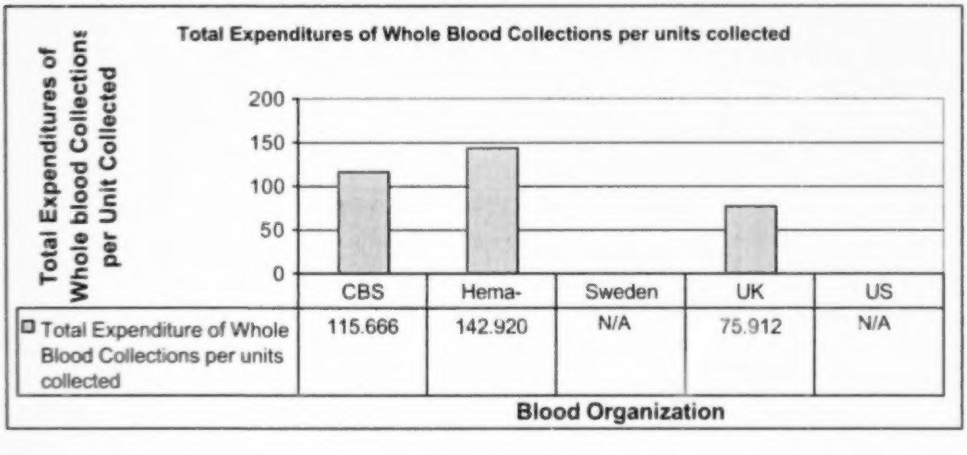
	CBS	Hema-	Sweden	UK	US
□ Total Blood Operation Expenditures per 1,000 Population	14,689	13,840	13,770	12,202	N/A

3.6.3 Cost of Whole Blood Collections Per Unit of Whole Blood Collected

Collections typically accounts for a significant portion of a blood agency's resources. In the benchmarking survey, the following definition of "Total Cost-Blood Collections" was provided:

"Total costs incurred for collection of whole blood such as the labour costs for collecting whole blood, medical supply costs such as collection containers, collection labels, collection supplies such as vacuum tubers, swab sticks, iodine, alcohol, gauge squares, bandages, lancets, capillary tubes, alcohol wipes, cotton balls, sodium citrate, needles, transfer packs, blood warming bags, etc. As well Total costs include all related management costs of conducting Blood Collections."

Exhibit 3-44: International Comparison of Whole Blood Collection Costs Per Units Collected



The results for this indicator show that Hema-Quebec has the highest Total Cost of Whole Blood Collections per Unit of Whole Blood Collected. CBS reported a lower Collections Cost Per Unit than Hema-Quebec but a higher cost than the United Kingdom. Sweden and the American Red Cross did not provide the data required for this indicator. All three of the blood organizations reporting do universal pre-storage leukoreduction. These cost variances warrant further investigation

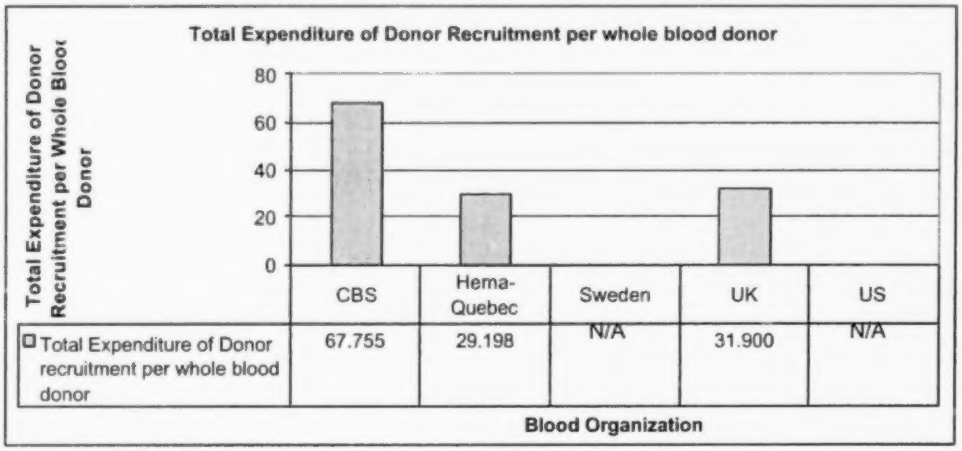
3.6.4 Cost of Donor Recruitment Per Number of Whole Blood Donors

In the benchmarking survey, the following definition of "Total Cost-Donor Recruitment" was provided:

"Total Costs incurred for recruiting donors such as labour and non-labour costs such as promotion and advertising costs, cost of blood donor clinics such as hall rental, catering costs and janitorial fees, donor card costs, donor awards costs, volunteer expenses (e.g. meals, travel, blood donor telephone recruitment costs and etc.), donor pin costs, promotional material (e.g. key chains, mugs, pens, t-shirts, etc.)"

The graph below shows that CBS' investment of $68 in Donor Recruitment Costs per Donor is significantly higher than both Hema-Quebec ($29 per donor) and the United Kingdom ($31 per donor). This may be a reflection of CBS' strategic priority to increase donor recruitment to address population growth and to offset the impact of the vCJD donor deferral policy. CBS has a relatively lower percent of donors per population compared to the other countries so it is not surprising that they would have to invest more in donor recruitment. However, population growth and donor deferrals are challenges that the comparator countries are facing as well

Exhibit 3-45: International Comparison of Donor Recruitment Costs Per Whole Blood Donor



3.6.5 Percent Donors Per Population and Average Donations Per Donor

These two indicators speak to the effectiveness of the investment in donor recruitment costs.

The table below shows that when compared to other blood systems, CBS has a relatively low rate of donors per population. These figures are based on the percentage of donors for the total population rather than the eligible population because different countries have different donor eligibility criteria.

Exhibit 3-46: International Comparison of Percent Donors Per Total Population

CBS	Hema-Quebec	Sweden	U.K.	U.S.
1.71%	2.10%	3.19%	3.75%	1.46%

Although a lower percentage of Canadians donate blood, the table below shows that the average number of donations per donor in Canada is slightly higher than in all of the comparator countries.

Exhibit 3-47: International Comparison of Average Donations Per Donor

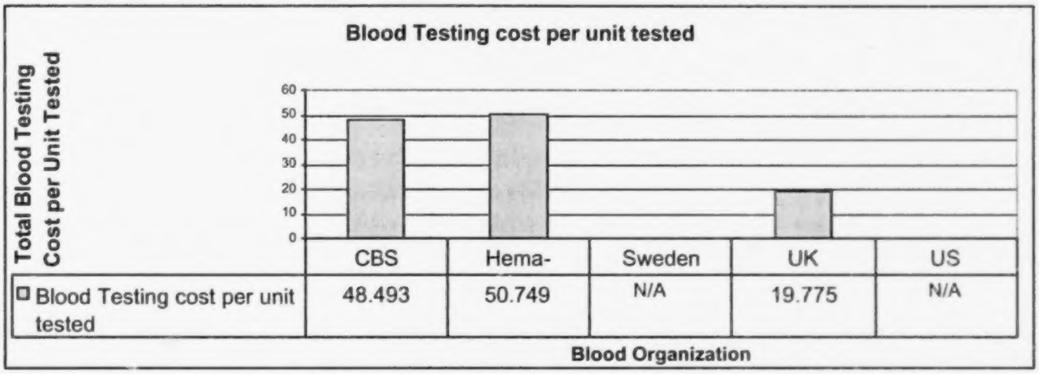
CBS	Hema-Quebec	Sweden	U.K.	U.S.
2.0	1.5	1.8	1.3	1.6

3.6.6 Blood Testing Cost Per Unit of Blood Tested

In the benchmarking survey, the following definition of "Total Costs – Donor Blood Testing" was provided:

"Total costs incurred for testing donor blood such as the labour for testing blood and medical supplies. Includes items for such tests as p24 Antigen, HbsAG, HCV, test kits, NAT and all related management of these test costs."

Exhibit 3-48: International Comparison of Blood Testing Costs Per Unit Tested



The results show comparable testing costs per unit for CBS ($49 per unit) and Hema-Quebec ($51 per unit). CBS and Hema-Quebec are regulated by the same regulator and perform the same tests. However, one difference is that Hema-Quebec outsources NAT testing because they currently do not have the facilities to perform this testing in-house. The facilities are being developed and Hema-Quebec plans to commence in-house NAT testing in November 2002.

Another difference is that based on the relative size of the populations served, CBS would be expected to achieve greater critical mass efficiencies in testing costs (e.g. purchase of test kits and reagents) than Hema-Quebec. This may be a factor in CBS' lower cost per unit tested.

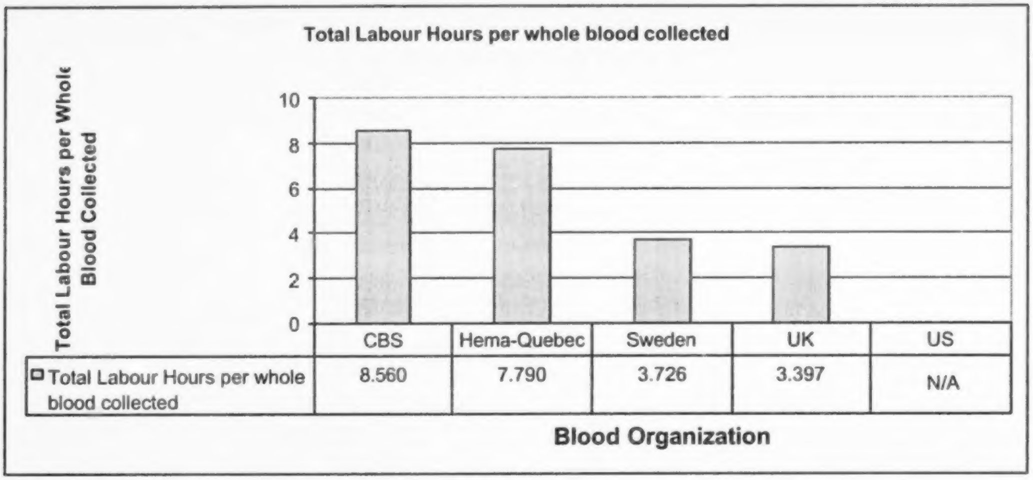
The results reported by the United Kingdom are significantly less at $20 per unit. There are two tests that are done in Canada that are not done in the United Kingdom: HIV-1, p24 Antigen and NAT-HIV. It is unclear at this level of analysis whether the fact that the United Kingdom does not perform these two tests accounts for the wide variance or if there are other factors involved.

3.6.7 Total Labour Hours Per Whole Blood Collected

A commonly used measure of productivity and efficiency is the Total Number of Labour Hours (for all functional areas) per Unit of Whole Blood Collected. Since this indicator does not involve costs it removes exchange rate factors and local economic factors from the equation.

In the table below, CBS labour hours for fractionation and UBMDR have been excluded from the calculation of total labour hours to increase comparability.

Exhibit 3-49: International Comparison of Total Labour Hours Per Unit of Whole Blood Collected



CBS reported the highest Total Labour Hours per Unit of Whole Blood Collected. However, the results are clearly bi-modal. CBS and Hema-Quebec reported results of 8.6 hours and 7.8 hours respectively. In contrast to the two Canadian blood systems, the two European countries reported very similar results of 3.4 hours for the United Kingdom and 3.7 hours for Sweden. In addition, blood system experts on the Expert Panel for this review estimate labour hours per unit collected in the US to be 3.4 hours – a figure comparable to the European results. A full explanation of these differences would require detailed study, however, one possible factor might be differences in the range of services and ancillary roles provided.

Based on the small number of indicators presented in this section, it appears that CBS is relatively well resourced compared to other countries. It is fairly difficult to evaluate different blood organizations around the world, given the exchange rate, purchasing price parity, cultural diversity, regulatory and policy decisions and other factors that affect the nature of the blood business. From the data that was received, it appears that other blood systems might be taking different approaches to various aspects of blood operations. These other approaches may be of interest to CBS and CBS will likely have much to offer these other countries as well. This type of international knowledge transfer and collaboration should be encouraged in the future.

Recommendation #35: There is a lot to be learned from exchanging information on financial and operational performance with other blood supply systems. It is recommended that CBS build on the international benchmarking process that was initiated for this review. The tool developed for this review provides an excellent starting point for ongoing benchmarking. It will be important to administer the survey with sufficient lead time for recipients to respond, taking account of seasonal issues.

3.7 Analysis of Key Balance Sheet Items

This section provides a brief analysis of key balance sheet items and issues.

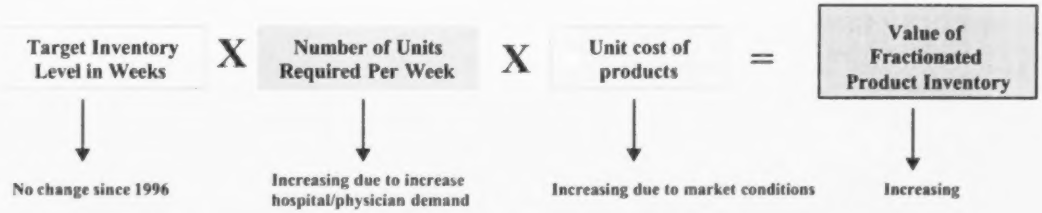
3.7.1 Working Capital Issues

The current working capital situation at CBS should be the number one priority addressed by the organization and its funders at this time. An explanation of this situation is provided below.

A significant proportion of CBS's cash is tied up in inventory. At the time of this review, CBS reported inventory of $78 Million. Of that $78 million, $64 million consists of fractionated products and approximately $10 million consists of medical supplies. Approximately $3 million of the inventory is Whole Blood.

When CBS was created in September 1998, a total of $27 million was provided to cover the cost of inventory for fractionated products. This figure has not changed over the last four years. The determination of the value of the fractionated inventory is illustrated in the diagram below:

Exhibit 3-50: Calculating the Value of Fractionated Product Inventory


Target Inventory Level in Weeks
X
Number of Units Required Per Week
X
Unit cost of products
=
Value of Fractionated Product Inventory
No change since 1996
Increasing due to increase hospital/physician demand
Increasing due to market conditions
Increasing

Because the demand and cost of fractionated products has increased significantly, there is an inventory coverage shortfall. CBS must use $37 million from its cash reserves to finance the unfunded portion of the fractionated inventory.

Recently, CBS has resorted to the use of "Restricted Funds" to fund this $37 million dollar shortfall. Prior to 2002, Transition Funding for activities such as the MAK implementation and research and development activities did not fully require all of the funds that had been allotted for these specific projects. But because the MAK Implementation is now fully underway and many research and development projects are quickly using up their resources, there is little cash available to finance the fractionated inventory.

CBS' Cash and Cash Equivalents, as shown on their Balance Sheet, is approximately $82 million. Of that $82 million, $63 million has been restricted for specific purposes and are considered "restricted funds". The remaining $19 million are "unrestricted funds" that can be used for other purposes at CBS' discretion.

The restricted funds include three main categories of funds:

- Transition Funds ($81 million federal contribution according to the MOU) - Transition Funds are funds set aside for specific purposes such as the funding for the MAK program and should not be used for any other purposes.
- Contingency Funds ($25 million according to the MOU) Contingency funds represent funds that have specifically been set aside for emergency situations and should not be used for any other situations.
- Federal and External Grants for Research and Development ($5 million per year federal contribution according to the MOU) - These funds are provided to fund specific Research and Development initiatives directed by the source of the funding and should not be used for any other purposes.

CBS has reported to the Provincial/Territorial Contacts that if this situation is not addressed, CBS potentially faces a scenario where they might not have sufficient cash in the bank to meet payroll requirements in approximately one year's time.

CBS has proposed four possible solutions to this problem:

1. Fund the Inventory of Fractionated Products Upfront
2. Arrange for a Line of Credit to Fund the Inventory of Fractionated Products
3. Decrease the Inventory of Fractionated Products
4. Ask Suppliers to Ship Products Directly to Hospitals

A fifth option of course is for CBS to get out of the fractionated product business and treat these products as drugs that hospitals would order directly from suppliers and pay for on their own. This would eliminate the inventory and financing issue for CBS. However, a disadvantage of this decentralized approach is the loss of buying power that comes with the purchase of large volumes on a national scale. Another issue is that CBS is the collector of plasma some of which is used to produce fractionated products. Currently the plasma that is collected is considered a national resource and not attributed to specific jurisdictions. This would have to be addressed if individual hospitals are paying for fractionated products.

Another option that might partially address but not resolve, the issue is to enforce the requirement that governments pay CBS at the start of the month.

The issue of how to fund inventory is an ongoing issue that must be addressed by CBS and its funders. The most critical issue is the use of restricted funds for purposes other than which they were intended. This practice cannot be allowed to continue.

Recommendation #36: CBS is facing a serious working capital situation as a result of large and growing volumes of fractionated product inventory. It is strongly recommended that CBS immediately cease the use of restricted funds to cover the working capital shortage.

Recommendation #37: CBS has identified a number of options for addressing the working capital situation and presented these to the P/T Contacts in June 2002. It is recommended that CBS move quickly to implement a strategy for alleviating the working capital issue. Based on the information that has been provided to the review team, we would suggest that the Members explore the option to finance the inventory as opposed to funding the value of the inventory upfront. However, the cost of financing and the ability of CBS/Members to provide some form of guarantee to a bank in order to access a line of credit must of course be important considerations. Discussions with financial institutions will be required to fully assess this option. Also, the lead Ministry should survey each province/territory about their preferred option and the capacity to contribute financially before proceeding. The recommended financing option should not be pursued in isolation. It should be combined with other strategies to address the growing costs of fractionated product including utilization management and vendor managed inventory models that were described previously in this report.

Recommendation #38: When communicating with P/T Contacts and Members, it is recommended that CBS link the working capital issue to the broader strategic policy context (i.e. it is more than an accounting problem, there is a need to manage product utilization).

3.7.2 Inventory Issues

In order to further understand the ramifications that inventory has on CBS' operations, the inventory turnover ratio has been calculated for the following categories. The inventory ratio indicates how often inventory is replenished in a given year.

Medical Supplies Inventory

	2002	**2001**
Inventory Turnover Ratio $	6.71	6.69

CBS completely replaces its medical supplies inventory approximately 6.7 times per year. This rate has remained fairly constant from fiscal 2001 to fiscal 2002.

Blood Collections Inventory

	2002	2001
Inventory Turnover Ratio	35.94	66.01

The variance above may be due to more product being collected as a result of the events of September 11, 2001.

Fractionated Products Inventory

	2002	2001
Inventory Turnover Ratio	3.84	4.71

In 2001/02, CBS completely replaced its fractionated products inventory approximately 3.84 times. This has decreased slightly from 4.71 in 2000/2001. But due to price increases the cost of inventory is increasing. Inventory turnover, in terms of units of inventory, is slowing down.

The dollar value of the fractionated products inventory has been increasing for two main reasons:

1) The volume of fractionated products required to be kept on hand has been increasing due to increasing demand
2) The unit price of fractionated products has been increasing (e.g. IVIG)

On average, CBS keeps approximately 8 to12 weeks worth of inventory in stock (depending on the particular product) and this target inventory level has remained unchanged since 1996. According to CBS, it is difficult to reduce inventory levels for fractionated products for several reasons including:

1) CBS has signed a five-year "take-or-pay" contract, which binds CBS to buy a certain amount of inventory every year or pay for it regardless of its necessity. This ensures that CBS benefits from a competitive price for fractionated products. Because fractionated product usage has increased significantly each year, there has not been a high risk for product wastage.

2) Promised delivery date and actual delivery date can vary, and if a delivery date is missed, then CBS will run the risk of not having the particular product in stock and they will run the risk of having to purchase the product on the spot market and purchase at potentially higher costs. The even greater risk is that patients will not have access to the products they require.

There are three types of Fractionated Product costs:

1. The cost of fractionating Canadian plasma provided by CBS and Hema-Quebec to fractionators that are located in the United States so the plasma can be converted to fractionated products.
2. The cost of purchasing the finished Fractionated Product from companies that are mostly located in the United States. Contracts for fractionated products are signed for multiple years. Orders for specific quantities are placed up to one year in advance.
3. The cost of purchasing plasma and/or finished Fractionated Product through the spot market, where the price is set via market conditions.

On rare occasions when CBS has not received deliveries on time they have had to purchase Fractionated Products on the open market. The costs are usually significantly higher, and thereby cause difficulties in effectively forecasting the value of fractionated product inventory. The major issue that challenges the suppliers is the nature of the product itself. Often with biological products, production lines are highly dependent on supply and environmental conditions. Some suppliers will offer to pay the differential cost difference between the spot market and the contracted price but not all suppliers will accommodate these requests. Even if suppliers agree to compensate for the difference, often there may be only one or two suppliers of a particular product, which causes an overall shortage and supply, as opposed to price, becomes the major issue.

Another issue that has arisen is the management of wastage in the fractionated product inventory. CBS cannot return product that is outdated (i.e. past its expiry date) to the supplier unless it is already short-dated when it is purchased. Typically CBS purchases products with one to two years dating which has resulted in a small amount of their products being outdated. Write-offs due to outdating are low when compared to volumes of products issued. Total write-off's for outdated products and losses due to damage was $643,000 in 2001/02 versus the $307 million issues. The largest write-off for outdating was a single product called Protein C, which was purchased when there was a large spike in demand and the write-off for this product was approximately $250,000. The balance of the $643,000 was due to small losses from breakages and other miscellaneous items.

Also, GMP requirements stipulate that CBS cannot accept returned fractionated products from hospitals without providing documentation that the product was kept within certain temperatures and environmental conditions. This is difficult as inventory management and storage is the responsibility of the hospitals once the blood has been delivered.

Different options should be examined to address this issue and cost-effectiveness must be a consideration. For example:

- The Australian Red Cross will soon be asking its hospitals to sign a Memorandum of Understanding indicating their compliance with proper storage and transport requirements for blood components and products.[30]
- Another option would be to initiate Fractionated Product inventory environmental condition monitoring at the hospitals. Therefore any product that is not required by the hospitals can be returned to CBS and re-distributed to other hospitals.
- A third option is the replacement or upgrading of the current FPMS (Fractionated Products Management System) computer system. The current system in place does not extend to the hospitals and allowing hospital inventory to be more visible to CBS may allow better inventory management techniques. As well FPMS does not provide good reporting and management tools and in order to obtain useful information, there are many manual activities that must be performed.
- A fourth option is to re-evaluate the amount of inventory that the main warehouse, each regional Centre and the hospitals should hold on hand.
- A fifth option is to evaluate the number of suppliers that are currently in place and to possibly investigate other vendors in order to better ensure competitive pricing and contingencies for delivery delays. This option has already been explored by CBS because they recently completed an extensive RFP process for fractionated products. They concluded that the procurement options are very restricted with a limited number of suitable suppliers in the market.

Recommendation #39: Funding the fractionation product inventory is an immediate challenge for CBS. Currently fractionated products and other supplies (with some exceptions) are shipped from the suppliers to warehouse facilities in Ottawa and then shipped to the Centres. It is recommended that CBS assess the feasibility of a virtual warehouse (for supplies and fractionated products) with vendor managed inventory that is shipped from the vendor directly to the regional Centres. In the case of fractionated products, the main supplier (Bayer) currently collects plasma for fractionation from each Centre. The possibility for the same truck that collects the plasma to also deliver the fractionated products should be explored (storage requirements such as temperature –control will be a consideration).

Recommendation #40: It is recommended that CBS evaluate the opportunity to implement the SAP Inventory Management (IM) module across all inventories at CBS. The evaluation should consider the ability of the IM module to meet regulatory requirements for sign-offs.

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[30] Website of the Australian Red Cross Blood Service.

3.7.3 Contingency Fund

As set out in the MOU, the Directors of the CBS may borrow money upon the credit of the Corporation for purposes of public health and safety not anticipated in the annual budget or overall financial forecasts in the strategic plan up to a maximum amount of 5% of its operating and capital costs as set out in CBS's most recent annual budget.

According to CBS, they require a minimum of $25 million in the contingency fund and if there is a safety threat that would cost more the $25 million, then CBS would have to discuss the funding with the Provinces and Territories outside of the normal budget process. In prior years, an allocation over and above the provincial/territorial contribution to blood operations was requested to replenish the contingency fund.

The contingency fund was funded at $19 million in fiscal 1999, $15 million in fiscal 2000 and $10 million in fiscal 2001, totalling $44 million. Expenditures to date have all been related to the variant Creutzfeldt-Jakob Disease with capital purchases and operating expenses totalling $20,995,909. Therefore, there is currently approximately $23 million in the contingency fund that is available for any unanticipated emergencies. As it is resting as cash, a portion of it has been utilized to fund the fractionated products inventory.

Recommendation #41: The MOU makes very brief mention of the contingency fund but leaves the implementation of the fund open to interpretation. It is recommended that the CBS Board (via the Executive Management Team) draft a policy regarding the use of the contingency fund and submit it to the Corporate Members for approval. The draft policy should describe the history of the fund, the size of the fund, the purpose of the fund, the approvals process for use of the fund and how the fund is to be replenished. Accompanying background information should outline what the fund has been used for in the past, how much has been used, when it was used and whether Board approval was obtained for past use. The underlying assets (cash) related to this fund should be segregated and not used as part of general operations.

3.7.4 Other Balance Sheet Items

Amortization of capital assets has been increasing from 1999 through to 2002, as a result of new equipment purchases. After taking over the operations of the Red Cross, CBS had to invest in purchasing new computer equipment, vehicles to replace the existing vehicles that were wearing down, and to generally bring equipment back to standard working conditions.

The Acquisition of Blood Supply System for $154 million in 1999 represents CBS' purchase of all of the assets comprising Canada's blood supply system (except for Quebec).

An increase in Long-Term debt in fiscal 2000 represents the mortgage agreement to finance the purchase of the Winnipeg Blood Transfusion Service Centre (WBTSC). Each year, CBS is committed to paying $1 million per year in principal payments to cover the cost of the WBTSC.

Provisions for Future Insurance Claims is called "outstanding losses" in the CBS Insurance (CBSI) statements. It is defined below:

"Outstanding losses and loss adjustment expenses represent the amounts needed to provide for the estimated ultimate cost of settling claims relating to insured events (both reported and unreported) that have occurred up to the balance sheet date. These amounts are based upon reports received from the ceding company plus an estimate for losses incurred but not reported based on the recommendations of an independent actuary using industry data.

A significant portion of the liability at the year end relates to blood diseases which are inherently difficult to quantify. The nature of latent diseases means that the diseases manifest themselves many years after the person was exposed to the cause. Therefore, not only is it difficult to determine the reporting patterns and reserves of the diseases currently known, due to the significant period between exposure and the manifestation of the disease of its symptoms, but it is also extremely difficult to determine reserves for diseases that have yet to be identified.

Whilst all provisions are periodically reviewed and evaluated in the light of emerging claim experience and changing circumstances, it is possible that changes in future conditions in the near term could require a change in the amount estimated. Due to the high limits of liability assumed by the Company, such changes could be material.

The resulting changes in estimates of the ultimate liability are recorded as incurred claims in the current period. Amounts recoverable from reinsurers are estimated in a manner consistent with the underlying liabilities."

A Members Resolution passed on August 24, 1998 allowed the Provinces and Territories to provide funding to the CBS up to $250 million which would allow CBS a vehicle to obtain Excess Blood Risks Liability of $750 million, in addition to the $250 million policy underwritten by the CBSI to establish and provide essential risk management services with respect to blood products liability and the medical malpractice risks arising out of the ownership, management and operation of the blood supply system by CBS.

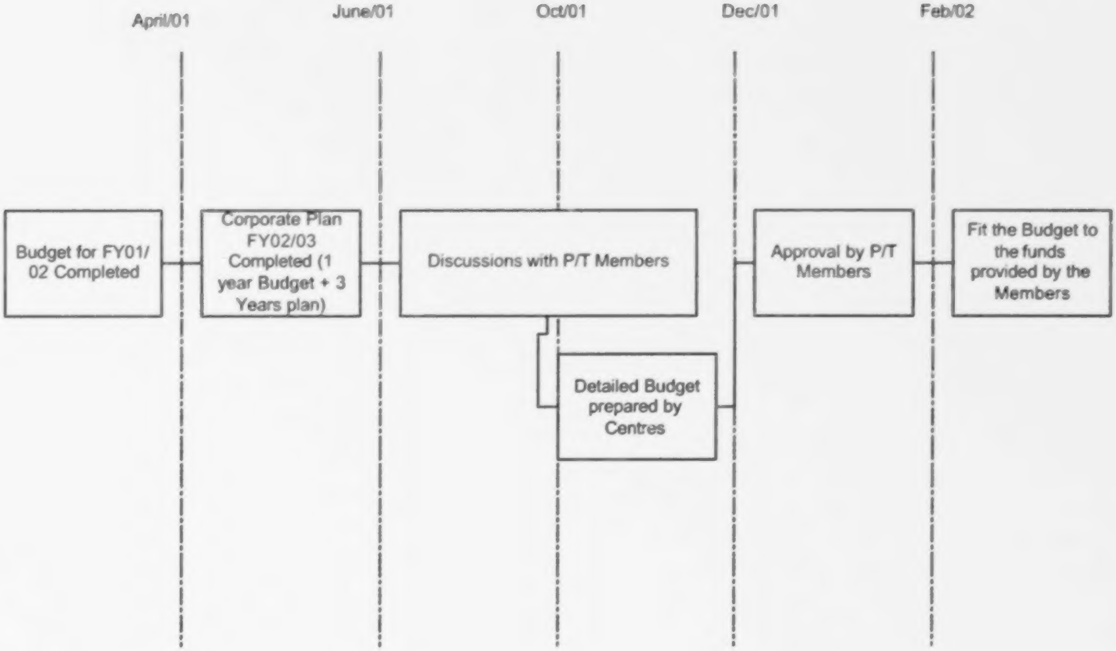
3.8 Multi-year Budget Submission

This section describes and assesses the multi-year budget submission process from the perspective of both CBS and the Corporate Members (the funders).

3.8.1 The Process and Format

The current budget process takes CBS approximately ten months to complete.

Exhibit 3-51: Multiyear Budget Timelines


April/01
June/01
Oct/01
Dec/01
Feb/02
Budget for FY01/02 Completed
Corporate Plan FY02/03 Completed (1 year Budget + 3 Years plan)
Discussions with P/T Members
Approval by P/T Members
Fit the Budget to the funds provided by the Members
Detailed Budget prepared by Centres

Shortly after the start of the 2001/2002 Fiscal year the budget process started for the 2002/03 fiscal year. The process starts with the preparation of the Corporate Plan for the following fiscal year, which consists of a one-year budget and a three year plan. The inputs into this process are:

- Previous year's budget
- Exchange Rates
- Shipment Requirements
- Forecasted Loss Rates

- Forecasted Inflation Rates
- Collections
- Expected Salary Increases
- Projects

In September/October, a meeting is held with the P/T Members to determine the dollar amount that is expected to be approved. For the 2002/03 fiscal year budget, the Members requested that three different scenarios be presented for review.

CBS currently requires that the Centres start to work on the detailed budget by the beginning of October in order to have the budget completed by March. The Centres are given targets in October for total budget in dollars, hours and collections. For the fiscal year 2002/03 the approved dollar amount was much lower than the targets that were sent out to the Centres. Therefore, after the dollar amount of the budget was approved by the P/T Members, the Centres had to go back, in February 2002, and adjust their budgets based on the funds available.

The Centres build their blood operations budgets from the bottom up, and start with the units of blood to be issued to hospitals in the fiscal year. SAP is utilized for the development of the budget, except for the salary information which is completed on Excel templates. After the implementation of the SAP HRIS and payroll modules, the budgeting of the salaries will be completed on SAP within a few years. The CBS would like to be able to provide the Centres with a target budgeted total for their Centre by the beginning of October so that the Centres could prepare the detailed budgets.

Recommendation #42: The budget process at CBS is extremely long. There is a tremendous amount of effort invested in the planning process that could be better spent on operations. It is recommended that the budget process be shortened to a maximum two to three months of active time. This will require the provision of provincial/territorial estimates on the amount of funding (or percent increase/decrease) likely to be available to CBS for the next fiscal year at a very early stage in the budget process.

Recommendation #43: It is recommended that the budget targets be established with the Members before the detailed budgeting is completed by the Centres.

Recommendation #44: The planning for salaries should be completed on SAP as soon as enough history is available in the system. This would eliminate the use of excel worksheets

Although CBS is required to submit a three-year corporate plan, the Corporate Members can only approve a one-year budget. The forecasted data for the subsequent two years provides the members with useful information on the long-term strategy of the organization and assists in anticipating future resource needs.

As noted above, the CBS budget is demand-driven – it is primarily based on a forecast of hospital demand calculated by trending the historical volume of hospital issues. This differs from other parts of the health care system which are generally managed on a capacity-constraint basis (e.g. a limited number of hospital beds or health care professionals). This is an important observation because the Provincial/Territorial Ministers that fund CBS likely deal with the capacity-constraint model for most other health care programs that they oversee.

Recommendation #45: It is recommended that the Corporate Members consider moving to an activity-based or volume-based budget model. The budget would become more focused on the volume of CBS outputs, rather than absolute dollars. Currently the funding formula for CBS is based on absolute dollars that are provided by the Members for a bundle of products and services. There is not a direct correlation of the dollars to the services that are budgeted or received. As the formula is structured today, if the volume of Red Blood Cells required by the provinces and territories increases, CBS must increase their collections, testing and distribution, without any additional funding. Also, if Members feel that the budget requested by CBS is too high, a budget reduction is communicated in terms of a dollar or percentage decrease in overall funding not in terms of an agreed upon reduced level of product or service.

Some of the benefits of an activity-based budgeting approach are:

- Links the planning process to the key performance measures
- Relates costs to activity versus an absolute cost factor
- Identifies the key drivers of cost of operations
- Enables the identification of manageable cost elements versus cost elements which are out of the control of the organization
- Promotes greater awareness of how costs relate to activities
- Can form the basis of a "contract" between the Members and CBS for CBS to provide a certain volume of product

A formula could be developed that is structured with fixed and variable cost components. The Members could review the fixed cost components and agree to a reasonable change, then agree to what would be included in the variable components. Members' expectations for operational efficiencies would be incorporated in to the development of the variable (i.e. unit cost) component. For example, in Blood Operations, performance targets could be set for areas like donor recruitment or finance. Pure variable costs such as blood bags and test kits would be planned for based on the volume of collections. The budget prepared for the Members would include the fixed costs spread across an agreed upon volume plus a variable cost component per unit of volume.

At a minimum, this approach should be considered for Fractionated Products, which are largely demand-driven, and possibly for blood operations. If activity-based budgeting is adopted for Blood Operations it will be important to identify performance measures that will be monitored regularly to ensure that incentives remain for maximizing cost-efficiencies. The current budget process for Patient Services and UBMDR should be maintained. The funding formula should be agreed to by the Members before the budget process begins. During the budget process CBS could populate the formula with the actual dollars, which would be presented to the Members for approval. This shift in budgeting approach would not change the Member budget approvals process. The approvals process should continue as it is and CBS would be required to return for Members approval of significant increases.

Recommendation #46: Currently, CBS is unable to report an accurate cost for each of the blood products it produces and the services it provides. It is recommended that CBS develop appropriate costing models to identify the unit cost of each of its products and services. This includes:

- development of unit costs for plasma and platelets (consideration should be given to contacting US blood centers that routinely produce price lists of specific blood products)
- re-evaluating plasma centre costs and distributing them to the cost of Fractionated Products; full costing should be performed to capture all direct and indirect costs of maintaining plasma collection operations.
- re-examination of the formula used for determining the cost per unit of red blood cells; the current formula produces a misleading result and also makes benchmarking with other blood service agencies very difficult. CBS currently reports this cost per unit with the inclusion of items such as UBMDR, research and development and plasma centres. CBS should calculate this performance measure without these extraneous cost items.

For example, by only including the following costs:

Exhibit 3-46: Sample Calculation of Cost per Unit of Whole Blood

Re-evaluation of Total Blood Operation Cost per Unit of Whole Blood Collected	**2002**	**2001**
Donor Recruitment	27,353,449	23,487,435
Blood Collections - Whole Blood	94,227,625	85,367,737
Manufacturing/Processing	10,850,991	9,230,203
Donor Blood Testing	42,793,563	40,100,201
Storage and Distribution	17,623,757	16,396,643
Quality Assurance and Quality Control	16,483,949	10,206,137
Administration/Overhead - National Level	45,183,392	39,527,203
Administration/Overhead - All Regional Blood Centres	40,231,729	39,271,727
Other	23,739,693	14,971,666
Sum of Total of Re-evaluated Blood Operation Costs	**318,488,148**	**278,558,952**
Whole Blood Collections	**803,625**	**740,909**
Total Re-evaluated Blood Operation Cost per Unit of Whole Blood Collected	**396.31**	**375.97**

This is only a starting point and these costs would have to be re-evaluated even further because the costs contained in the Administration/Overhead also include resources associated with Patient Services, UBMDR and Fractionated Product overhead costs. An exercise may be required to fully break apart these costs using a form of activity-based costing in order to truly predict an accurate cost of blood operations.

The multi-year budget submission process has been affected by the strained relationship between the CBS and the Corporate Members, particularly when it comes to financial issues. Corporate Members and P/T Contacts feel that CBS has not always provided them with the information they need to support decision-making on the budget and corporate plan. CBS feels that the information needs have not always been clearly spelled out but that they have responded appropriately to specific information requests.

Recommendation #47: Corporate Members are concerned that the information provided does not always meet their needs. CBS should maintain a close working relationship with the P/T Contacts, Lead Ministry and others that can help them proactively identify the information needs of the Corporate Members.

Recommendation #48: CBS should ensure that all budget submissions are developed in accordance with Member requirements. It is critical that Members needs are met, even if additional information/options are included as well.

The budget submission and corporate plan must highlight the application of a cost/benefit/risk framework to support requests for new programs and initiatives.

It appears that there is no template for submission of the multi-year budget submission. CBS would develop the format for submission. In the past, the information needs of the Members were communicated in a reactive fashion. That is, a set of questions and requests for clarification would be prepared after the initial submission had been presented. In 2001, there is evidence of the emergence of a more proactive approach. In June 2001, the Provincial/Territorial Blood Liaison Committee prepared a "Checklist for Consideration in Ongoing Budget/Business Planning Processes". The checklist provides very specific and helpful direction for the multi-year budget submission. The various questions and requests for supplementary information prepared over the years should have also serve to provide CBS with insights into the expectations of the Corporate Members.

Recommendation #49: Building on the "Checklist for Consideration In Ongoing Budget/Business Planning Processes" (June 2001) the Corporate Members (via the P/T Contacts) should develop a template for the CBS budget and corporate plan. (a sample is attached in **Appendix G**)

Recommendation #50: The template included in Appendix G includes a table for the reporting of budget information by functional area (e.g. donor recruitment, collections, testing, etc.). CBS does not currently report data to the Members in this fashion so it will be difficult to provide comparative historical data on this basis. However, expenditures by functional area will provide Members with a better sense of what funds will be used for. It is therefore recommended that the reporting of expenditures by functional area be piloted for the next budget cycle, in addition to the current budget format. Members should assess usefulness of the information provided and advise CBS on the most effective format to use going forward.

Recommendation #51: CBS should continue its plan to split fractionated products into a separate set of books to ensure that the costs are kept separate from those of blood operations. It is also recommended that CBS further split their reporting of blood operations into the main business activities: Blood Operations, Patient Services and UBMDR. There are different cost drivers for each of these business areas, therefore it would be important to report them separately so that the performance of each area could be monitored and managed. This does not eliminate the need to also present a consolidated budget that provides the Corporate Members with information on the total overall budget figures.

Recommendation #52: CBS should consider using a rolling 12 month forecast approach. The 12 month rolling forecast would mean that there would always be a budget or forecast for 12 months out at any time. As each month passes, another month is budgeted at the end of the cycle. (A rolling forecast approach is currently in place for Fractionated Products.) The benefits of using a rolling forecast approach are:

- A more externally focused, market sensitive process
- A more direct linkage of the organization's strategic plan to top-level plans through the lowest level departmental detail
- More forward-looking, decision making data
- A more streamlined process with lower resource requirements; and
- An increased accountability within operating units, driving business action, not rationalization

If rolling forecasts are not prepared, then quarterly forecasts should be prepared within the fiscal year to update the plan with any known changes.

3.9 *The Finance Function*

This section will address four areas: achievements in relation to the finance function, the structure and processes of the finance function, financial reporting and financial performance indicators.

3.9.1 Achievements in the Finance Function

CBS has made improvements to almost all aspects of its finance function since its inception. Some of the achievements to date include:

- Organization
    - Centralized the accounting function in Ottawa. This includes the accounts payable, purchasing, accounts receivable, general accounting and reporting thus eliminating the accounting organizations that existed in each of the Centres.
    - Created a shared services environment for transactional processing, but still have a finance role at the Centre level to assist the Centre manager.
    - Added skills to the finance group such as cost accounting that were not previously there, and are required.
- Roles and Responsibility
    - Finance roles have been redefined.
    - Accountabilities are more clearly defined than in the past.
- Process
    - Standardized the transactional processes such as accounts payable, accounts receivable and payroll across the organization. Previously each Centre had its own processes and supporting systems.
    - Data for all Centres is available through the central repository and can be reported by anyone who has the security access to the system.
    - Labour hours and position codes are now available and will enable efficiency reporting and analysis and assist with future planning.
- Technology
    - The CBS has implemented the SAP financial modules. This includes the general accounting, reporting, purchasing, accounts payable, Human Resource Information System and payroll, and are piloting inventory management.

3.9.2 Finance Structure and Processes

CBS moved to a shared services model for its transactional processing of accounts payable, general ledger processing and reporting and payroll. This model will enable the CBS to realize economies of scale as they improve their efficiencies. The current organizational structure has direct line reporting relationships, and clear accountabilities. Each Centre has a finance person who reports to the Centre Director. The role of the Centre finance staff differs between Centres, and there is not a formal relationship between them and the Head Office finance group. This could be changed to ensure that the accountabilities for these roles are clear and that knowledge is transferred.

There are approximately 83 Full Time Equivalents (FTEs) in the Finance group which includes; Payroll, Time Administration, Accounts Payable, Purchasing, Treasury, General Accounting, Budgeting and Financial Analysis, Cost Accounting, Transportation Operations, and Warehouse. This does not include the finance staff that are based at the Centres. It is important to note that the employees at the Centres perform both administrative functions and finance functions. The range of functions performed include logistics (fleet), receiving, shipping, inventory, facilities, SAP, super-user and trainer, and budget.

Recommendation #53: CBS should re-evaluate their financial staff requirements at both the regional centres and at the head office to eliminate duplicate functions. There are a significant number of finance staff at both the regional Centres and at the head office that are performing functions such as preparing financial reports and conducting budget forecasts.

There are a number of opportunities to improve the processes within the finance function, reduce the number of transactions and thus the number of FTEs involved.

The accounts payable group alone has 12 FTEs and the purchasing group 15 FTEs. The Fractionated products purchased primarily constitute roughly half of the organization's expenditures. These products are purchased from one or two vendors, therefore should involve minimal transactional effort. The remaining expenses would include labour, medical supplies and overhead. The process for the purchase and payment of the remaining items should be reviewed and improved to gain efficiency and optimize the use of the SAP tool that is in place. The CBS recognizes this and would like to improve the process through:

- Imaging invoices
- Implementing electronic faxing capability of purchase orders right out of SAP
- Creating more contracts in the system
- Utilizing the pay upon receipt functionality (ERS)
- Using more purchase orders to speed up the processing in accounts payable.
- Automating the purchasing card upload
- Reducing the number of approvals (currently five approvals are required on requisitions)
- Automating the travel and expense process (currently using a manual form)
- Making payments through electronic funds transfer (EFT), instead of cheque

Recommendation #54: There are approximately 12 staff working in Accounts Payable which seems high given that close to half of the organization's expenditures are to one or two major suppliers for fractionation and there is only one supplier of blood bags. It is recommended that CBS conduct an assessment of the resourcing of the Accounts Payable function and alternative approaches to providing this function.

Recommendation #55: In addition to initiatives already identified by CBS, there are other opportunities to improve efficiencies in the financial function that should be explored. Based on the experience of other organizations where a top tier ERP system is in place like SAP, there is the potential to save in the range of 25% in purchasing and accounts payable by simplifying and standardizing the processes and moving to shared services. High value practices would also need to be implemented to fully realize the potential benefits available. For example, in the purchasing and accounts payable area to realize savings the following changes to the process could be implemented:

- Negotiate national contracts for commonly purchased items
- Set up catalogues for common repeated purchases; all purchases for these items would be purchased via catalogue
- Use purchase orders for all purchases
- Two way matches (purchase order to receipt) are set up for payments, eliminating the receipt and processing of the invoice
- Payments are made via electronic funds transfer and cheque payments are discouraged.

By negotiating national contracts and ensuring that all purchases for items on the catalogues are purchased via the catalogues there is also an opportunity to realize savings on the purchase price. There will be an opportunity to negotiate better pricing given the improved negotiating position CBS would be in by leveraging the national purchasing volume. It is important to note that in the case of CBS the savings potential relates mainly to non-medical supply costs.

Recommendation #56: One of the findings from the review is that some key products have a single supplier. There are advantages and disadvantages to having a single supplier. The advantage is usually access to volume discounts. A disadvantage or risk is the total reliance on one supplier in the event that the suppliers operations are discontinued either temporarily or permanently. While some organizations have chosen to adopt a policy around always using multiple suppliers there is value in addressing this issue on a case by case basis that would consider all of the relevant facts. For example, the balance of costs such as extra SOPs and training if there are multiple suppliers with slightly different products vs risks (contingency plans) vs benefits. It is recommended that CBS conduct an assessment of the costs, benefits and risks of single vs multiple supplier arrangements for key items including blood bags. This approach should also be taken for high volume, high cost fractionated products that also tend to be purchased from one or two suppliers. CBS should continue to use a rigorous RFP process to obtain competitive prices on single source products.

SAP financials were implemented in six months with completion in April 1999. This was a relatively fast SAP implementation.

Recommendation #57: CBS was able to standardize the financial processes across the organization when SAP was implemented, but they should now go back and identify additional benefit opportunities. They have a very good tool in place, but there is a need to review the processes to ensure that they realize the benefit of having such a tool.

Another area of opportunity is time reporting. CBS implemented the SAP HRIS, Payroll system in June 2002. All time reports are sent to one of three Centres (Ottawa, Calgary or Saint-John) for manual inputting. This is a very time consuming process that currently involves 23 FTEs.

Recommendation #58: It is recommended that CBS consider the implementation of employee time-entry as a next-stage project for SAP. The examination of the benefits associated with the elimination of manual time-entry should be included in the proposed post-implementation review of the HR-Payroll system. The savings associated with the elimination of the paper-based time capture system should be part of the business case validation that precedes this project.

3.9.3 Financial Reporting

Financial reports for the CBS are currently prepared from SAP. SAP is the central source of financial data for the organization. There is a tremendous amount of information available through the financial system. Currently there are 450 users of the system that can view reports from any of the Centres and head office. Reports are viewed on-line, with the exception of head office where some reports are still printed and distributed.

The CBS tends to provide very detailed reports of the financial results. They are currently reporting separately for Fractionated products, and all other blood operations including the UBMDR, and Patient Services, and have completed the last corporate plan in this manner. The last business plan contained much better explanations and narratives to the statements than in previous years. The analysis is much more indepth and provides good explanations to some of the variances. However, the previous year actual or forecast was not included, which would provide a comparison as to what the difference is in the proposed plan against current operations.

In order to manage the entire operation of the blood system, all of the required information needs to be readily available. For Blood Operations, the CBS does not currently have a perpetual inventory system in all locations, therefore up to date inventory reports are not available. They are currently piloting the SAP Inventory Management module for their medical supplies inventory. For the other Blood Operations inventory items, they perform monthly counts to verify inventory quantities. The investment in inventory plays a key role in the cash flow requirements. Full information on inventory is required to ensure that the right product or item is in the right place at the right time, as well as to manage inventory quantities and investment. This would require implementing a perpetual inventory system for all inventories that could be accessed when required.

Recommendation #59: It is recommended that CBS prepare reports that place more emphasis on summarizing the issues and actions, rather than providing accounting detail. CBS generates many different reports, such as the monthly Management Reports, that offer a large amount of detail and insight in the operations of CBS. This does not however give a good overview of the operations quickly and would require a significant amount of time to understand the report. Therefore, CBS should consider creating a "dashboard" that highlights only the key performance indicators for the user and the major factors affecting its costs.

Recommendation #60: CBS also needs to pay close attention to their audience when preparing reports. This is especially important for the Members where there may be turnover in the positions and the new person in the role may have a different understanding and expectations from CBS. It is recommended that both the internal and external users of the financial information be surveyed on a regular basis to ensure that they are receiving the information required to perform their role (this can be done on a formal or informal basis).

3.9.4 Assessment of CBS Financial Performance Measures

CBS has developed a number of key performance measures that are being monitored by the Operations Division. These measures will be described in more detail in section 5.1. This section will focus specifically on financial performance measures.

The key performance measures for the organization address blood safety, quality and to some extent cost effectiveness. The measures do not however address overall cost effectiveness such as the overhead functions, or the other costs per unit that would be incurred other than labour. Although budget variances are routinely reported to the Executive Management Team and the Board as part of the Finance reports, financial performance relative to budget is not included as part of the corporate performance measures framework.

Recommendation #61: It is recommended that CBS establish performance measures to assess the performance of the financial function. Possible measures for consideration include:

- Purchasing/Accounts Payable
    - Percentage of payments that are non-purchase order related
    - Number of invoices processed per Full-Time Equivalent (FTE)
    - Number of active vendors
    - Number of blanket purchase orders
    - Percentage of payments made via Electronic Funds Transfer (versus cheque)
- Billing/Accounts Receivable
    - Number of invoices processed per FTE
    - Percentage of invoices that are error free
    - Days Sales Outstanding (DSO)
    - Percentage of Bad Debts
- Time Capture
    - Number of time reports processed per FTE
    - Ratio of Time Capture employees to Total employees
- Overall Finance
    - Cost of the Finance function as a % of total expenses (done as a % of Total Revenue in most orgs)
    - Number of days from the close of the month to the creation of management reports
    - Total number of days to prepare the annual budget

4. Information Technology Review

4.1 Information Services

The Information Services (IS) department is a centralized support function operating out of CBS' Lancaster Road location in Ottawa. The IS department is managed by a Chief Information Officer (CIO) who reports up through the Vice President of Corporate Services/CFO.

IS is further segmented into four operating units each led by a director. The four units are:

- Information Technology Services
- Enterprise Business Systems
- SAP Business Systems
- Strategic Informatics Services

IS employs approximately 133 staff which are a combination of CBS staff and contracted consultants (approximately 94 FTE staff to 39 FTE consultant split). The total operating budget for IS is $14 M with an additional $28 M being allocated to CBS' four transformational initiatives (e.g. MAK implementation, Centralized Contact Centre, Consolidated Testing, and UBMDR). The current IS budget represents roughly 4% of CBS' approximately $700M in funding.

Recommendation #62: With the potential implementation of large projects such as the national contact centre and the Client Relationship Management application, it is recommended that CBS consider the creation of a central project management office (PMO). The PMO should employ an accepted set of project management practices and tools to centrally manage the multiple issues and dependencies the proposed initiatives are expected to create.

Recommendation #63: The PMO described above should be charged with coordinating the implementation of the IS recommendations contained in this report.

Recommendation #64: As part of any new IT initiatives or the creation of a project office, it is recommended that CBS review its change management and training planning. Initial implementation and refresher training for applications should be managed centrally by IS.

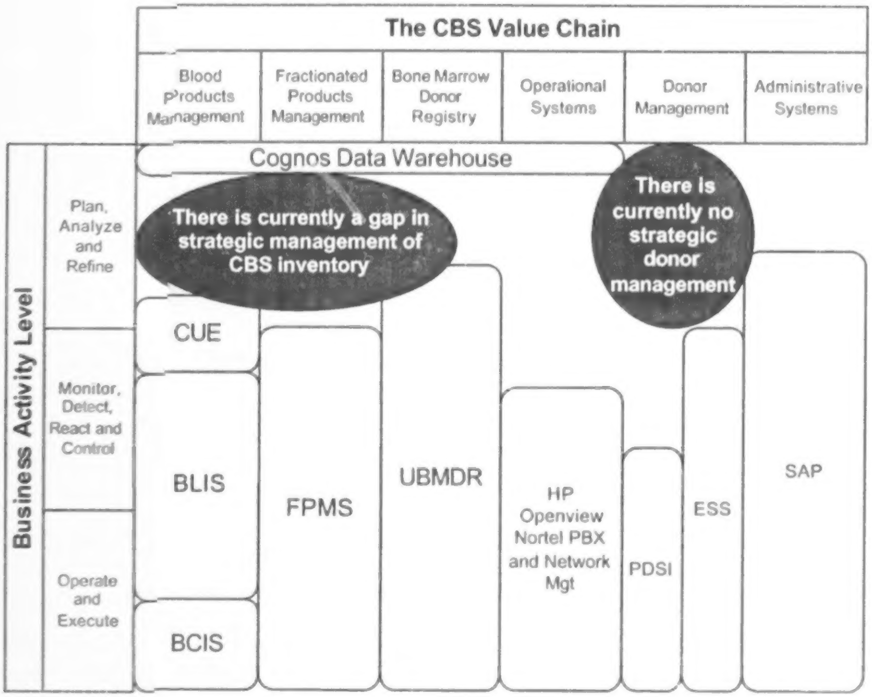
4.2 IS Management

CBS has aggressively moved to centralize the management of technology infrastructure from the IS location. During the review, the following components were noted as being centralized:

- Wide Area Network (WAN) – all CBS locations are connected through a managed network solution contracted with Bell Canada. All WAN infrastructure components have been standardized to Cisco equipment.
- Telecom – All phone systems within CBS have been consolidated onto a single Nortel phone PBX platform. Switch and account management can be controlled centrally and the implementation of a single handset across all CBS locations allows for quicker issue resolution and swapping of units.
- PCs / Laptops / Servers – All office technology procurement has been centralized and CBS has consolidated all its disparate desktop platforms onto a single vendor . The elimination of multiple PC platforms allows for better stability and management of technology issues.
- CBS has implemented a single enterprise storage area network (SAN) which allows robust high-capacity storage for all non-regulated systems.
- Operating Platform – CBS is operating on Windows NT4 for all its workstation and server platforms. The elimination of multiple operating systems and the move to Windows 2000 should reduce overall management costs.
- Development Platforms – CBS only develops applications on three platforms: Lotus Notes, Microsoft InterDev, and SAP. An additional layer of development is conducted in business intelligence reporting from CBS' Data Warehouse using the Cognos suite of tools. The minimization of platforms allows CBS to better manage systems and focus on internal skills development.
- Office equipment consolidation – The purchase and contract management of all photocopier and other office equipment has been centralized with IT who has been able to negotiate better purchase and support contracts with fewer vendors.

The IS department has adopted an "agile" approach to IT strategy where the time horizon on the plan has been reduced from five years to approximately two years. This approach allows CBS to update its plan annually. The CBS IS department has also successfully employed technology portfolio management as a tool to support its planning and budgeting. The IT strategic approach allows for a better focus on CBS operational drivers as its projected time horizon is not excessively distant, and the portfolio management approach allows it to align IT spending with overall CBS business drivers.

Exhibit 4-1: The CBS Value Chain


The CBS Value Chain
Blood Products Management
Fractionated Products Management
Bone Marrow Donor Registry
Operational Systems
Donor Management
Administrative Systems
Business Activity Level
Plan, Analyze and Refine
Monitor, Detect, React and Control
Operate and Execute
Cognos Data Warehouse
There is currently a gap in strategic management of CBS inventory
There is currently no strategic donor management
CUE
BLIS
BCIS
FPMS
UBMDR
HP Openview Nortel PBX and Network Mgt
PDSI
ESS
SAP

Recommendation #65: As part of its PC and laptop renewal, it is recommended that CBS review its PC platform purchasing options so that it is not purchasing all its PC assets at once. CBS should consider staggering its capital purchases based on accepted hardware lifecycles (e.g. renewing one third of its desktop PCs each year assuming a three year lifecycle) or leasing with its current hardware vendor. Either approach would allow CBS to better manage the capital implications of hardware purchasing and integrate into the annual planning process. Any negotiated contract should include hardware platform version freezing so that CBS has similar machine platforms if it decides to purchase machines across a drawn-out timeframe.

Recommendation #66: It is recommended that CBS consider the implementation of an internal chargeback or cost allocation mechanism for telecom and office equipment costs. The current inability of IS to hold other business units accountable for costs or to influence behaviour may lead to ongoing increases of this budgetary component.

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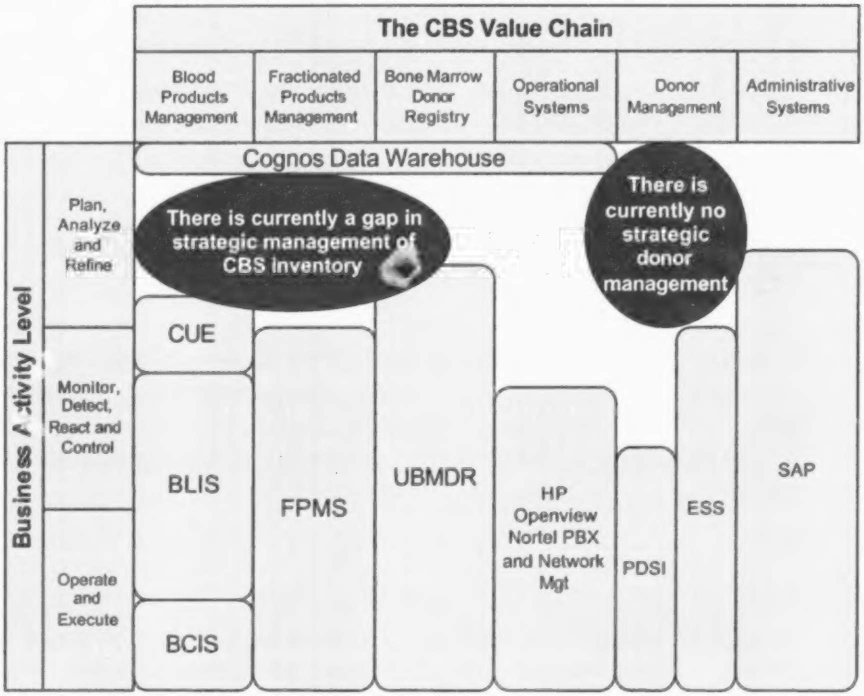
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4.3 Operations Management

Through IS a consolidated service desk has been deployed that allows for a single point of contact (SPOC) for all requests for assistance. The service desk has played a critical role in dealing with user assistance requests. The help desk has implemented the ITIL Service Desk framework for processing calls and provides 06:00-20:00 staffed coverage with off-hours call-back capability. The service desk utilizes HEAT for trouble ticket tracking and monitoring of performance levels against internal service level agreements. Through the consolidated infrastructure, help desk staff are able to perform remote desktop takeover to assist users without on-site staff. The IS department conducts regular user satisfaction reviews and has consistently attained a 95% satisfaction rating among polled users.

Network management is proactively monitored using HP Openview and Netfinity tools. The use of the management tools allow for quicker root cause analysis using the hierarchical views and discovery/polling capabilities to identify faults.

Continuity management is currently being assessed internally by IS and there is currently a hot-failover site at the CBS Alta-Vista location. This site allows for full redundancy for the blood applications. It is noted that the failover equipment is often used for data analysis work which allows for the analysis of current data without impacting the performance of the production system at the Lancaster site.

Recommendation #67: The current division of administration and operations management within IS could potentially lead to functional overlaps should SAP be selected for Client Relationship Management or if the current data warehouse functionality begins to impact on administrative systems. It is recommended that CBS review the organizational impacts and synergies of these two groups and consider re-aligning responsibilities.

Recommendation #68: It is recommended that CBS continue to review its disaster response capability and consider the adoption of an accepted framework such as ITIL Service Management for evaluating its availability and continuity requirements. The adoption of any mitigation measures for enhancing availability or expanding continuity measures should be included as part of the IS portfolio planning process.

4.4 Systems to Support Blood Operations

Due to the regulatory requirements, information technology that is responsible for blood products must be specially segregated. The current system is the BLood Information System (BLIS) which contains donor records and donation history. The

BLIS system is built on a legacy platform which interacts with multiple databases. A current issue with the BLIS system is the fragmentation of donor information across provincial database instances. This lack of integration has necessitated the implementation of some manual processes, including Visiting/Moved Donor procedures for when donors present themselves at other than their home centre clinics.

There are two additional regulated systems used for blood management, the Confidential User Exclusion (CUE) system and the Blood Component Issuing System (BCIS). Both the CUE and the BCIS systems are stand-alone applications that operate on dedicated workstations in the blood centres. The CUE system provides a donor with a final opportunity to stop their donation from being further processed and transfused. The CUE system does not store any donor information or interface with the BLIS system and is completely reliant on bar codes for information. The CUE system is also responsible for generating paper-based reports to ensure that units are identified for disposal.

The BCIS system allows the blood centre to issue a packing slip for all blood products that are shipped out of the blood centres. The BCIS system consolidates all shipping and unit information in a locally stored database that would allow the centre to lookup where blood components have been shipped. Currently there is no centralized database of shipping information and regular backups of the BCIS databases are performed by centre staff. BCIS data is now captured in the Data Warehouse to provide a national view of shipping information for analysis purposes. Until MAK is properly implemented, there is no national 'operational' inventory, ordering or shipping system.

Currently, all technology components of the BLIS system are securely segregated from all other CBS systems. The requirement that all changes to the BLIS system including non-software modifications such as hardware upgrades be subject to a detailed regulatory review is very onerous.

The current system for monitoring blood supply levels nationally consists of an excel spreadsheet and Lotus Notes system that is accessible by each of the blood centres. Each centre is expected to update their daily inventory levels via a spreadsheet at the end of the day or if there is a significant change in product levels (i.e. shipping of a large amount to another centre). An automated process that runs every 15 minutes takes the inventory information from each centre's spreadsheet and generates a national inventory view that is accessible by all centres. This daily inventory information is also captured in the Data Warehouse for analysis purposes, including a data cube for corporate discard analysis.

Currently, BLIS and other regulated systems are securely managed following Health Canada guidelines. These guidelines do add significant costs to the development and support of regulated systems.

Recommendation #69: The current burden of five and seven part regulatory approvals for all changes to the BLIS system is burdensome. It is recommended that CBS and Health Canada explore the creation of pre-approved procedure for break, fix and maintenance procedures.

Recommendation #70: The current time-lag in getting clinic results (total donors) from the BLIS system makes strategic planning of additional clinics difficult. The integration between the systems should be strengthened and possibly could be bridged via the current Cognos data warehouse without requiring external experts or additional applications.

4.5 Systems to Support Fractionated Products

The current system for managing all fractionated products is the Fractionated Products Management System (FPMS). The FPMS system is based on a legacy Oracle database that allows each data centre to access inventory levels of local (Centre) shelf stocks and the centralized warehouse adjacent to the Alta Vista location. The current application is covered by the same regulatory requirements as the BLIS system for all system changes.

4.6 Bone Marrow Information Systems

Bone marrow information is not covered by the same regulatory framework as the blood systems. CBS recently updated the Unrelated Bone Marrow Donor Registry with the internally developed UBMDR 2002 application. UBMDR2002 consists of a web-enabled user interface (Microsoft IIS running ASP, VB Script, Java Script, XML, and XSL) with an MS SQL database back end. The system allows for the management of donor and patient information, donor appointment scheduling, blood sample management, and donor to patient matching. As an improvement over the previous system, UBMDR2002 allows for the recording and tracking of foreign donors being considered for Canadian patients.

The donor to patient matching algorithm implemented in UBMDR2002 has the flexibility to determine matches using any combination and resolution of serologic and DNA typings.

4.7 Donor Management Systems

There are currently two systems in place to manage donor telemarketing and clinic scheduling: The PDSI is a purchased donor scheduling and call-list generation system that is made available to centres through Citrix. The use of Citrix allows secure remote access to the application and allows CBS to maintain a single instance of all telemarketing information.

The Event Scheduling System (ESS) is a CBS developed application that oversees clinic scheduling and resource requirements. The ESS system is available to authorized CBS users through a web browser on the internet.

CBS is currently assessing the feasibility of developing donor appointment functionality within ESS. This would provide an excellent fit with the current clinic booking functionality. The use of an integrated application as the single access tool for appointment and clinic scheduling would allow CBS the opportunity to:

- Remove the need for manual transcribing of clinic information from ESS to the legacy PDSI donor scheduling system and provide additional efficiencies of clinic management from an integrated system;
- Deploy a single user interface (web browser) which could moderate administration and training costs;
- Replace PDSI and the related annual licensing and support costs by upgrading to a single web interface, as well as;
- Reduce Citrix ISA client deployments and potentially recover the licensing costs and dedicated thin-client servers.

Recommendation #71: It is recommended that CBS consider eliminating the PDSI system and include the donor scheduling and call list generation capabilities into the ESS system until the Central Contact Centre and CRM initiatives are complete. This project could use in-house development expertise, while the savings from discontinuing PDSI would come from the cancellation of license and support costs.

Recommendation #72: The use of the CPM model used in planning clinic resources in ESS does not reflect actual clinic capability. In densely scheduled clinics, donors often have to wait too long for service and leave frustrated. It is recommended that the resource scheduling model be revised to reflect actual clinic capability.

Recommendation #73: The remote capabilities of PDSI are limited and often result in database issues such as faulty entries if a replica of the database is re-synchronized with the network version. It is recommended that CBS explore the use of mobile technologies or the expansion of remote access capabilities as part of the replacement of PDSI to allow for field staff to have updated schedules and donor information. It is expected that a limited pilot of a packet based mobility solution could be tested for less than $10,000 (wireless card and usage metering) if there are no major software revisions required to access the application remotely.

Recommendation #74: The current ESS/PDSI does not allow CBS to strategically telemarket to donors outside of clinics they have frequented in the past. As part of any new functionality, it is recommended that CBS explore a decision support system that would allow telemarketers to solicit potential donors if a clinic is closer to their home than one they have used in the past. This functionality would ideally be integrated into the successful CRM application that CBS selects. This capability might allow additional strategic capability such as directing donors to clinics that are not historically operating at capacity.

4.8 Administrative Systems

CBS has implemented SAP R3 to support its administrative functions. Currently CBS has implemented the FI and CO (Financial and Comptrollership) modules and a limited amount of the MM materials management module. In spring of 2002 the HR-Payroll SAP module was implemented across CBS.

All SAP modules have been implemented with the assistance of an external systems integrator. The current SAP system contract was signed prior to CBS assuming IT operations from the Red Cross and review of the original per-seat costs indicate that CBS pays a single fee per user seat regardless of the level of use. A review of the overall licensing costs indicates that CBS should be able to negotiate a different licensing arrangement that would bring it in line with other SAP users. Through the local SAP user groups, CBS has found out what large government SAP users are paying for user-seats and has negotiated incremental-cost tiers for new users.

Recommendation #75: It is recommended that CBS review its SAP licensing agreement and continue to benchmark their per seat costs against other Ottawa companies and government organizations. CBS should continue to explore aggressive enterprise re-pricing contracts that allow for tiering of user types as additional modules are considered. Should additional modules be identified for implementation, CBS should consider completely re-negotiating its licensing and review potential structures such as enterprise pricing (e.g. my SAP enterprise licensing). CBS through discussions with the Treasury Board has begun re-negotiating SAP seat costs and should be able to half what it currently pays per seat. Should the use of SAP be expanded such as what would occur with on-line time reporting an enterprise or tiered license could save $1,000 to $2,500 per user from the current licensing costs.

5. Performance Review

This chapter of the report is divided into three parts:

- The first part describes and assesses the performance indicators used by CBS.
- The second part of the chapter examines the performance of CBS in relation to each of the guiding principles set out in the Memorandum of Understanding.
- The third part of the chapter looks at CBS performance from a customer perspective. It includes the results of the hospital survey.

5.1 Mechanisms for Measuring Performance at CBS

5.1.1 Current Operational Performance Indicators

CBS has recently established a "Strategy Map" which includes a set of performance measures. According to CBS Quality Policy, the aim is to have performance measures that "are challenging, visible and understandable". In order for performance measures to be effective, they must align with the overall organizational strategy. Performance measures are the means by which the strategy is translated into measurable activities that direct the organization's behaviour and performance. At CBS, the measures are grouped using a balanced scorecard approach. The groupings cover the four priority areas for the organization:

- Customers – Enhance Customer Service
- Internal Process – Improve Quality and Safety
- Financial – Increase Cost-Effectiveness
- Learning and Growth – Greater Employee Satisfaction

There are two levels of performance measures: corporate measures and operational measures. Corporate measures were introduced by CBS in September 2001 and the operational measures in April 2002.

The operational performance measures are reported by each Centre. According to CBS, "these measures are selected based on their ability to act as gauges of the divisional ability to support the four corporate objectives."[31] The Operations Division has the lead role for implementing the operational performance measures. The key contact person is the Director, Operational Effectiveness. Measures that relate to "improve quality and safety" are reported in separate reports produced by the Safety and Performance Management Division in collaboration with Operations.[32]

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[31] CBS Operations Divisional Performance Measures, April 2002.

[32] IBID.

A list of the corporate and operational measures is provided in the table below:

Exhibit 5-1: Corporate and Operational Measures

Strategic Priority Area	Corporate Measures	Operational Measures
Customer Perspective: Enhance Customer Service	Hospitals • Hospital satisfaction on measures of: adequacy and timeliness of components and fractionated products, level of patient services provided, relevance and timeliness of CBS information • Percent of components issued versus ordered • Additional measures to be developed to promote optimal utilization Donors • Percentage increase in Collections (whole blood and plateletpheresis) • Volume of plasma shipped to fractionation • Average yearly donation frequency • Donor satisfaction survey results • Donor turnaround time Public • Public survey results	• New Donors • Donor Frequency • Issues/Orders Ratio • Donor Satisfaction • Branding/Awareness • Public Confidence Trust
Internal Process Perspective: Improve Quality and Safety	Process Efficiency • Incidence of preventable reportable errors • Incidence of preventable post-donation information • Number of component indate discards over components produced • Incidence of adverse transfusion events related to CBS activities • Percentage of key suppliers to total suppliers • Cycle time on critical processes • Percentage of CBS component outdates (by component) • Percentage of time spent on administrative support functions in comparison to manufacturing	• Blood Component Quality Control Results • Biological Product Deviation • Repeat Regulatory Audit Observations • Repeat Corporate Audit Observations

Strategic Priority Area	Corporate Measures	Operational Measures
	functions • Number of repeat observations received from Health Canada National Focus on Key Functions • Cost of testing per donation tested • Number of units released without complete testing • Labour costs in telerecruitment • Cost of component produced	
Financial Perspective: Increase Cost-Effectiveness	• Productivity Index • Working Capital Ratio	• Labour Hours/Whole Blood Collections • Labour Hours/Red Blood Cells Manufactured • Budgeted Collections vs. Actual • Red Blood Cell and Whole Blood Discard Rate • Platelets, LRF Discard Rate • Apheresis Platelet Discard Rate • RP and RP<15 Components Shipped for Fractionation
Learning and Growth Perspective: Greater Employee Satisfaction	• Number of change requests submitted by internal staff • Amount of research funds raised through extramural grants and contracts • Percentage of change requests implemented successfully • Internal customer satisfaction • Number of work instructions • Total training time per work instruction • Rate of staff turnover	• Quality of Internal Corporate Messaging

Prior to these measures being introduced the performance measures that CBS was using were very high level and not based on activity.

At this stage, it appears that the implementation of the operational performance measures is further ahead than implementation of the corporate measures. Targets have been established for the operational performance measures but not for all of the corporate performance measures. A "Guide to Operations Divisional Performance Measures" has been prepared which describes reporting frequency, ownership (each performance measure has an identified owner), report run dates, data sources, formulas for calculating the indicators and reporting process.

The timeliness of the information reported varies according to the performance measure. For example, the April 16/17, 2002 CEO Report to the Board included data up to either January 2002 (blood product deviations), February 2002 (hospital demand) or March 2002 (collections, audit results, occupational health and safety) depending on the specific measure. Also, the performance measures differ in the frequency that they are reported. For example, the hospital issues/orders ratio is reported monthly but the employee satisfaction measure is reported annually.

The CEO went on a nation-wide tour of all the Centres to promote the new performance measurement model. This tour was very well received by the staff in the Centres. Centre staff report that the new Strategy Map means they now have a clear set of expectations. Centre staff appear to be knowledgeable of the performance measurement process and Centres are reporting the required information to Head Office. At the Head Office level, the information is consolidated, analyzed and reported up to the Executive Management Team and the Board of Directors on a regular basis.

Recommendation #76: It is recommended that CBS complete the "Strategy Map" in a timely manner by identifying performance measures and targets for all of the objectives identified. For example, there are currently no measures in place to address the goals of awareness of blood and blood products, establishment and maintenance of positive and productive relationships or the establishment of the CBS as a Centre of Excellence in Research and Development.

Recommendation #77: It is recommended that CBS consider including the following additional performance measure in its Strategy Map and/or operational performance measures:

- The hospital-based indicators of adequacy and efficiency such as elective surgery cancellations, platelet reductions, hospital discard rates, etc.
- Overhead costs per unit, or overhead costs as a percentage of total costs.
- Indicators related to fractionated products (e.g. outdate rates, issue to order ratios)
- Indicators to measure the performance of the finance function (see financial review section)
- Indicators related to educational sessions held by CBS (local and national)
- Number of research papers published or conference presentations
- Improvement in relations with external stakeholder groups (this could be measured through a survey by an independent group)

Recommendation #78: It is recommended that CBS re-visit the targets that have been established for some of the key performance measures with a view to "raising the bar" for these measures. Examples include:

- The target for meeting hospital demand should be to meet 100% of hospital demand every month (rather than the current target of 95% of hospital demand nine out of 12 months of the year)
- The target discard rates for whole blood, red blood cells and platelets should be re-examined based on international benchmarks

Recommendation #79: It is recommended that CBS establish targets for each Centre for costs by activity level. Current operational performance measures are not specific to Centres. For example, there is an overall target to reduce the cost per unit of red blood cells by 5% regardless of how the Centre is currently performing.

5.1.2 Performance Framework for Planned Future Operations

Within the Strategy Map, corporate performance measures have been identified for some, but not all, of the transformation initiatives. Under the internal process quadrant, there are a set of measures under the heading of "national focus on key functions". These measures relate to consolidation of testing, consolidation of donor contacts and consolidation of manufacturing. It is planned that measures will also be developed for consolidation of blood component inventory.

Under the "learning and growth" quadrant, the intent is to include measures related to the design, validation and implementation of MAK Progesa. At the time of this review, these measures had not yet been specified.

It is not clear if specific operational targets have been established to measure the impact of the transformation initiatives, for example, a targeted reduction in costs. Also, it might be appropriate to raise the bar on existing targets once the Transformation initiatives have been introduced.

5.2 CBS Performance Relative to the Guiding Principles

The terms of reference for this review state that: "the Ministry of Health requires a full and comprehensive review of the current and projected activity of Canadian Blood Services (CBS) as it relates to the Memorandum of Understanding…" To address this requirement, the performance findings in this section are organized according to the ten guiding principles described in the MOU. These principles are:

1. The safety of the blood supply is paramount.
2. Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged.A national blood supply program should be maintained.
4. A fully integrated approach is essential.
5. National self-sufficiency in blood and plasma collections should be encouraged
6. Accountabilities must be clear.The system must be transparent.
8. A cost-effective and cost-efficient blood supply program for Canadians should be encouraged.
9. Voluntary donations should be maintained and protected.
10. Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained.

5.2.1 The safety of the blood supply is paramount.

The principle "safety is paramount" has emerged as the cornerstone of the Canadian blood supply system. To assess how well CBS has responded to this principle, several factors were examined:

- Safety initiatives introduced by CBS in each functional area
- Quality monitoring initiatives and audit results
- Customer perceptions of safety
- Stakeholder perceptions of safety
- Public perceptions of safety

5.2.1.1 Safety Initiatives Introduced by CBS, by Functional Area

Donor Screening

Donor screening is the first safety valve in the blood supply system. In an effort to improve donor screening (and ultimately the safety of the blood supply), CBS has added six new questions to the donor screening form that was used by the Canadian Red Cross. The six new questions are:

- Have you spent a total of 3 months or more in the United Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man, or the Channel Islands) since January 1, 1980?
- If you have been in the United Kingdom since 1980, did you receive a blood transfusion or any medical treatment with a product made from blood?
- Have you spent a total of 3 months or more in France since January 1, 1980?
- Have you spent a total of 5 years or more in Europe since January 1, 1980?

- In the past 12 months have you been in jail or prison?
- Have you had sex in the last 12 months with anyone who has used cocaine?

Another question has been slightly modified from "in the last three years, have you been outside Canada, other than the U.S. and Europe?" to "in the last 3 years, have you been outside Canada, other than the U.S.?"

Recommendation #80: The wording of the current donor screening form is rather advanced, particularly for people whose first language is not English. The ability of donors to clearly understand the questions on the form and give an informed consent is critical from a risk management perspective. It is recommended that CBS review the current donor screening form with a view to simplifying the wording. The review should include an assessment by a "plain language" specialist as well as input from donors and the public.

Recommendation #81: It is recommended that CBS explore innovative methods of donor screening that are less reliant on the literacy level and language capacity of donors. For example, consideration could be given to the use of interactive video technology which is in place at some blood centres in the U.S.

CBS has also changed its donor criteria in response to the risk posed by variantCJD. Potential donors that have visited certain European countries within a particular timeframe are deferred. This policy was instituted after an extensive consultation process and approval from Health Canada. The table below shows the trend in donor deferrals since 1996/97. On average, about 20% of donations are deferred for various reasons. In 2001/02, vCJD referrals represented 3.75% of all deferrals and 0.7% of all donations. Initially, only travellers to the United Kingdom and France were deferred but in September 2001, the list of excluded countries was broadened in response to new evidence.

Exhibit 5-2: Trend in Donations and Donor Deferrals

Year	Number of Donations	All Deferrals	vCJD Deferrals
1999/00 (8 months)	614,665	124,821	6,858
2000/01	927,222	177,301	4,316
2001/02	1,007,941	200,104	7,504

Collections

In the Collections area, the most significant safety improvement was the introduction of pre-storage leukoreduction in 1999. This improvement was a requirement introduced by the regulator.

Leukocytes are white blood cells, one of the types of cells in human blood. Their function is to help fight off foreign substances such as bacteria, viruses and abnormal cells in an effort to avoid disease. When leukocytes are transfused to another person, however, they do not provide any benefit to the recipient. In fact, these leukocytes, when contained in blood, are not well tolerated and have been associated with adverse transfusion reactions, such as fever (the most common, occurring in about one percent of red blood cell transfusions and up to 30 percent of platelet transfusions) and chills, as well as other serious transfusion problems, such as transmission of cytomegalovirus (CMV) and human T-cell lymphotropic virus (HTLV-I/II). In addition, leukocytes can cause the formation of antibodies that make future transfusions less likely to be effective and more likely to cause a reaction. White blood cells are known to cause transfusion reactions and removing contaminated leukocytes provides a purer, and hence, safer product. Leukoreduction is the removal of contaminating white blood cells from blood products before the blood is transfused. In this process, blood is passed through a filter that separates leukocytes from other blood components (red cells, platelets, plasma).[33]

CBS performs leukoreduction on all whole blood collections. Other blood service agencies (Hema-Quebec, United Kingdom, American Red Cross, Sweden) have also introduced leukoreduction.

Testing

CBS conducts a variety of tests on all blood that is collected. The table below illustrates how the testing done by CBS compares to other blood service agencies.

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[33] Universal Leukocyte Reduction Q&A, Website of the American Red Cross.

Exhibit 5-3: International Comparison of Blood Tests Used

Test	CBS	Hema-Quebec	Sweden	UK	US
Hepatitis B Surface Antigen (HBsAg)	Yes	Yes	Yes	Yes	Yes
Antibodies to the Hepatitis B Core (Anti-HBC)	No	No	Yes	No	Yes
Antibodies to the Hepatitis C Virus (Anti-HCV)	Yes	Yes	Yes	Yes	Yes
Antibodies to the HIV, Types 1 and 2 (Anti-HIV-1,-2)	Yes	Yes	Yes	Yes	Yes
HIV-1 p24 Antigen	Yes	Yes	No	No	Yes
Antibodies to Human T-Lymphotropic Virus, Types I and II (Anti-HTLV-I, -II)	Yes	Yes	Yes	In Progress	Yes
Syphillis	Yes	Yes	Yes	Yes	Yes
Nucleic Acid Amplification Testing (NAT) HIV	Yes	Yes	No	No	Yes
Nucleic Acid Amplification Testing (NAT) HBV	No	No	No	No	No
Nucleic Acid Amplification Testing (NAT) HCV	Yes	Yes	No	Yes	Yes

There are ongoing upgrades to CBS testing systems, software and package inserts. But since CBS has been established, two new tests have been introduced to improve the safety of the blood system. These tests are NAT-HCV and NAT-HIV. NAT stands for Nucleic Acid Amplification Testing. NAT-HCV is for detecting the Hepatitis C virus and NAT-HIV is for detecting the Human Immunovirus which causes AIDS. NAT-HCV was introduced in the Fall of 1999 and NAT-HIV was introduced in May 2001.

NAT is a relatively new test that works by detecting low levels of viral genetic material present when an infection occurs but before the body begins producing antibodies in response to the virus. The traditional tests require the presence of antibodies to trigger a positive test result. NAT significantly reduces the "window period" or the time between initial infection and when the virus is first detectable using antibody tests.

Studies have shown that NAT can detect Hepatitis C in blood donated by someone who contracted the disease 14 to 28 days prior to donating, whereas traditional tests detect the virus after about 70 days. For HIV, NAT can detect HIV in blood donated by someone who contracted the disease 11 days prior to donating, compared to 16 days for traditional tests.

NAT testing requires a very sterile and complex, laboratory environment. There are strict limitations around the flow of air and objects between the various rooms where the different stages of the testing are done. CBS purchased the technology necessary to implement NAT from Roche Canada. NAT laboratories have been created at four locations – Vancouver, Toronto, Ottawa (National Testing Laboratory at Head Office) and Halifax.

NAT is being used on an investigational basis in order to demonstrate its efficacy in detecting HCV and HIV. The regulator did not issue a "directive for NAT testing but they did make it a "condition of license". The regulator expects CBS to investigate NAT's efficacy. The data collected from the investigation will be used to support the manufacturer's application for licensing of the testing kit as a blood donor screening test in Canada.

There is a lot of controversy surrounding NAT testing because it is a very expensive test to introduce and, to date, the number of "window cases" discovered around the world has been quite small. Exhibit 5.3 above shows that CBS, Hema-Quebec and the U.S. Blood Centres are using NAT testing for both HCV and HIV. The UK system uses NAT-HCV but not NAT-HIV. Sweden has chosen not to implement NAT at all. Recently, Scotland announced its decision to stop NAT-HIV effective July 1, 2002. Scotland will continue to conduct NAT-HCV.

When CBS announced the introduction of NAT-HCV it stated that "mathematical models indicate that NAT will detect an additional four to six cases of HCV each year in Canada."[34] However, in the close to three years since NAT-HCV has been used in Canada, only one confirmed window case has been discovered. The UK has had a similar experience with NAT-HCV. A recent journal article reported that "from a total of about 7 million donations tested in the UK over the past 24 months (to end of September 2001), only three HCV-infected donors have been identified, instead of the predicted 50 to 100".[35] There have been no confirmed cases found by NAT-HIV in Canada.

Recommendation #82: CBS is currently using NAT testing for HCV and HIV on an investigational basis. NAT-HCV has been used for approximately three years. Given the high cost of the tests, the very small number of window cases and the fact that other countries that introduced NAT are reconsidering it use, it is recommended that CBS conduct a re-evaluation of NAT testing including a thorough cost-benefit-risk assessment based on evidence that has been gathered during the investigational stage (e.g. total cost expenditures, total number of confirmed window cases, other benefits) and on international experiences.

Distribution

In October 2001, CBS implemented manual expiry date labelling on blood bags before they are shipped to hospitals. Now labels show the expiry date in addition to the collection date. This initiative should improve the safety of the blood supply by making it easier and faster for hospitals to identify when products will expire.

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[34] "Inside Circulation – A newsletter for CBS staff and volunteers", Vol. 1, No. 1, October 1999, page 1.

[35] "The UK blood transfusion service: over a (patent) barrel?", The Lancet, Vol. 359, May 18, 2002, page 1713

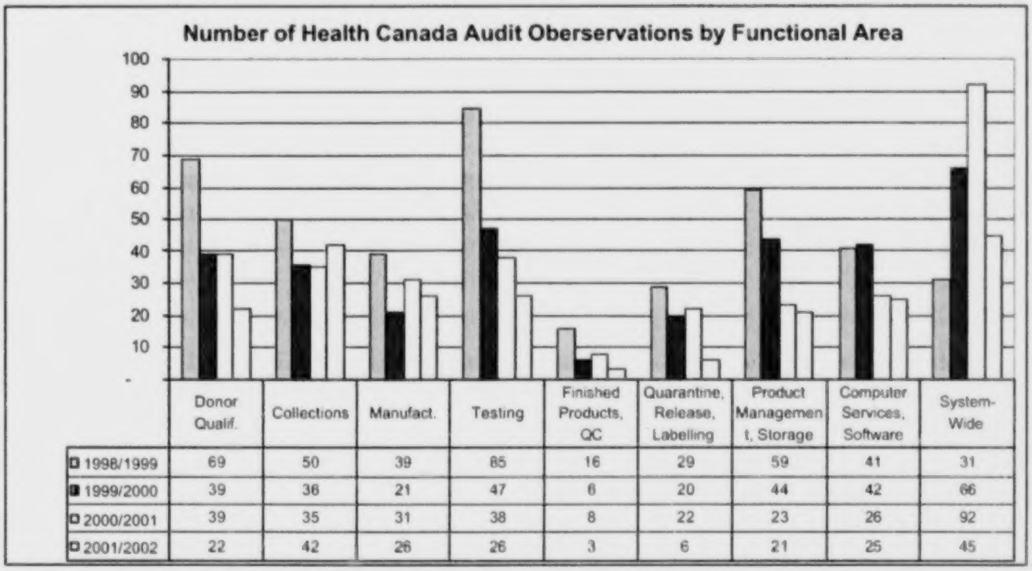
Quality monitoring initiatives and audit results

A variety of quality monitoring initiatives are in place to ensure that safety procedures are being used appropriately and consistently.

First and foremost are the audits by the regulator, Health Canada. Health Canada audits each Blood Centre and the Head Office once per year and follow-up visits occur as required. CBS tracks the number of audit observations by functional area, by Centre and over time. Audit results are posted on the CBS public website.

The graph below shows the number of audit observations by functional area for the past four years. This data does not address the severity of the observation. There has been a positive downward trend in the number of observations in most functions (i.e. donor qualification, testing, finished products quality control, quarantine, release and labelling, product management and storage and computer services). For the past three years, most of the observations have been of a "system wide" nature. Collections is one area where the number of audit observations has not decreased significantly over the years and in fact there was an increase in observations in 2001/02 over 2000/01. CBS attributes this to the introduction of numerous deferral policies for vCJD which challenged the Collections function.

Exhibit 5.4 – Number of Audit Observations



	Donor Qualif.	Collections	Manufact.	Testing	Finished Products, QC	Quarantine, Release, Labelling	Product Management, Storage	Computer Services, Software	System-Wide
□ 1998/1999	69	50	39	85	16	29	59	41	31
■ 1999/2000	39	36	21	47	6	20	44	42	66
□ 2000/2001	39	35	31	38	8	22	23	26	92
□ 2001/2002	22	42	26	26	3	6	21	25	45

CBS has also tracked trends in the number of audit observations, by Centre over the past four years. Caution must be used in interpreting this data because again it does not address the severity of the observation, nor does it account for variations in size and scope of functions carried out by the various Centres. To adjust for these variations, the table below converts the number of audit observations for each Centre into a rate by dividing by the volume of collections at each Centre.

Exhibit 5-5: Health Canada Audit Observations Rate Per Collection Volume, By Centre (2001/02)

Province	Number of Audit Observations	Number of Units of Whole Blood Collected	Observations Per 1,000 Units of Whole Blood Collected
BC & Yukon	14	106,810	0.1311
Calgary	9	67,275	0.1338
Edmonton	8	52,488	0.1524
Regina	10	24,411	0.4097
Saskatoon	11	27,601	0.3985
Winnipeg	21	52,845	0.3974
Sudbury	16	29,273	0.5466
London	16	63,008	0.2539
Hamilton	7	78,844	0.0888
Toronto	18	150,823	0.1193
Ottawa	21	49,309	0.4259
New Brunswick	7	30,727	0.2278
Halifax	10	35,794	0.2794
Newfoundland and Labrador	15	23,654	0.6341

CBS also has a number of internal quality monitoring systems. There is a Quality Systems Department that oversees Quality System Associates that work in each of the Centres. To ensure objectivity, the Quality System Associates report to Head Office. Their role is to conduct regular audits of all of the departments in the Centre. They audit compliance with both Standard Operating Procedures and Centre Operating Procedures. Quality System Associates must also approve new Centre Operating Procedures.

Standard Operating Procedures (SOPs) also contribute to the safety of the blood supply by outlining processes to ensure that all functions are performed safely and consistently. In 1996, the Canadian Red Cross introduced a Regulatory Compliance Project that resulted in the production of hundreds of SOPs. With the establishment of CBS, some new SOPs have been written and some have been changed. As of April 2002, 961 SOPs had been identified. CBS staff estimate that about 300 to 400 of these SOPs have actually been implemented. SOPs for Collections and Component Manufacturing have been rolled out to the Centres with the corresponding training. SOPs have been written for NAT and are being used. The reasons why all of the SOPs have not yet been implemented include time and resource limitations. In the meantime, Centres use COPs to fill the gaps.

5.2.1.2 Customer perceptions of safety

The hospital survey asked hospitals to comment on the quality of the products they receive from CBS. The categories available were: very good, good, neutral, poor and very poor. Eighty-four percent of respondents felt that CBS is "very good" or "good" at continuously monitoring the process to ensure integrity of components.

The survey also found that 35% of respondents felt that product quality had improved since 1998, while the majority (55%) felt that there had been no change. Only 1% of respondents felt that quality had worsened. A total of 201 respondents answered this question.

5.2.1.3 Stakeholder perceptions of safety

Interviews with a variety of stakeholders consistently identified ensuring safety as a strength of CBS. Most stakeholders felt that safety of the blood supply had improved. According to one physician, " the product is now so safe that any further improvements are almost hypothetical".

5.2.1.4 Public perceptions of safety

In a recent public survey, sponsored by CBS, respondents were asked how safe they considered receiving a blood transfusion to be. Almost half of respondents (47% - rating of 6 or 7 on a 7-point scale) considered receiving blood to be safe. This is up from 37% in 2001.

The same survey also found that 81% (compared to 83% in 2001) of respondents agree that "the blood system in Canada is safer today than it was five years ago."

Seventy-three respondents (compared to 72% in 2001) agree that "if they needed a blood transfusion, they would be confident that Canada has an adequate and safe supply of blood."[36]

In summary, safety has been the primary focus of CBS since its inception. The organization has clearly embraced the principle that safety is paramount.

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[36] Winter 2002 General Public Research Program Final Report, Submitted to Canadian Blood Services by Ipsos-Reid Corporation, April 2002, page 21.

5.2.2 Adequacy and security of supply of all needed blood, components and plasma fractions for Canadians should be encouraged.

Adequacy is a function of supply and demand. To address this principle, CBS must supply the amount of blood components and products required for therapeutic purposes. According to the Memorandum of Understanding, a responsibility of CBS is: "maintenance of a capability to address inventory imbalances (shortage/surplus) to minimize waste and ensure adequate supply." This requires effective demand planning or forecasting. Different approaches are used for blood operations and fractionation.

For blood operations, forecasting demand has traditionally been based on historical trends in the volume of components issued to hospitals. Efforts are underway at CBS to improve the demand planning process. In the future, more emphasis will be placed on impact analysis of new or changed hospital programs. This information will be gathered from hospitals by the Centres.

For fractionation, demand planning is based on maintaining target inventory levels that have been established for each product. The target inventory levels were determined by an assessment that was conducted in 1996 by the Canadian Red Cross. The inventory levels were re-examined and confirmed in 2001. The target inventory levels prescribe the number of weeks of product that must be kept on hand for each product in order to meet demand. The weekly demand is determined by analyzing historical trends. Demand planning for fractionated products is a challenge because sometimes a commitment to order volumes must be made a year in advance to secure the required volumes from the suppliers.

The balance of this section will discuss:

- adequacy in terms of blood components
- adequacy in terms of fractionated products
- emergency preparedness
- contingency funds

5.2.2.1 Adequacy of Blood Components

From a supply perspective, the volume of blood collected has increased every year since 1998. The table below shows the annual volumes of whole blood, plasma and platelets collected. The percentage increase/decrease over the previous year is shown in parenthesis.

Exhibit 5-6: Trend in Units of Blood and Blood Components Collected

Blood Component	1998/99	1999/00	2000/01	2001/02
Whole Blood	687,556	723,086 (4.9%)	740,909 (2.4%)	803,625 (8.5%)
Plasma by Plasmapheresis	35,339	35,017 (-0.9%)	36,995 (5.4%)	37,279 (0.8%)
Platelets by Plateletpheresis	12,451	14,026 (11.2%)	16,122 (13.0%)	18,336 (12.1%)

From a demand perspective, hospital orders have increased each year. The table below shows the annual volume of orders of red blood cells from hospitals and the annual volume of red blood cells issued to hospitals. The percentage increase/decrease over the previous year is shown in parenthesis.

Exhibit 5-7: Trend in Volume of Hospital Orders and Hospital Issues for Units of Red Blood Cells

Blood Component	1999/00	2000/01	2001/02
Hospital Orders	743,709	776,710 (4.3%)	798,025 (2.8%)
Hospital Issues	646,403	677,239 (4.6%)	714,963 (5.3%)
Issues as a % of Orders	86.9%	87.2%	89.6%

Although collections are increasing, hospital issues have not kept pace with hospital orders. However, the proportion of orders that are met has improved each year, rising from 86.9% in 1999/00 to 89.6% in 2001/02.

The following graphs illustrate how hospital orders and issues vary by month.

Exhibit 5-8: 1999 – 2001 Monthly Demand (Orders)

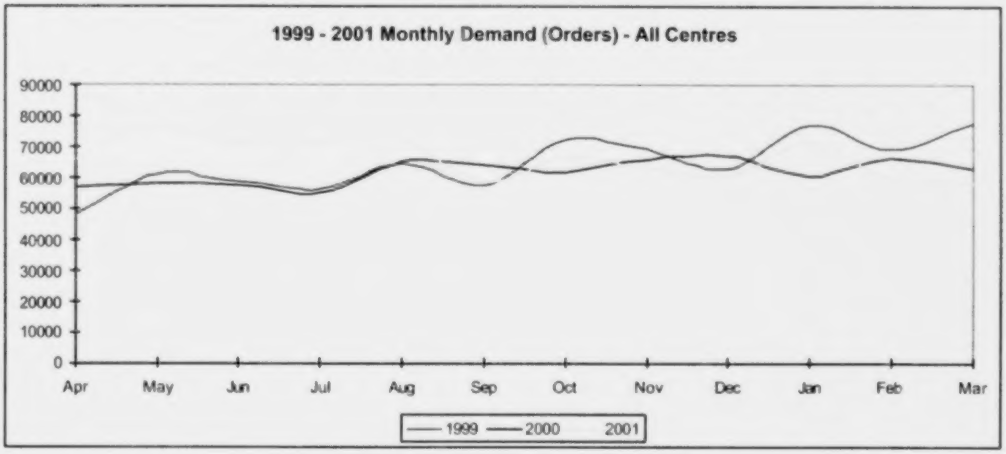
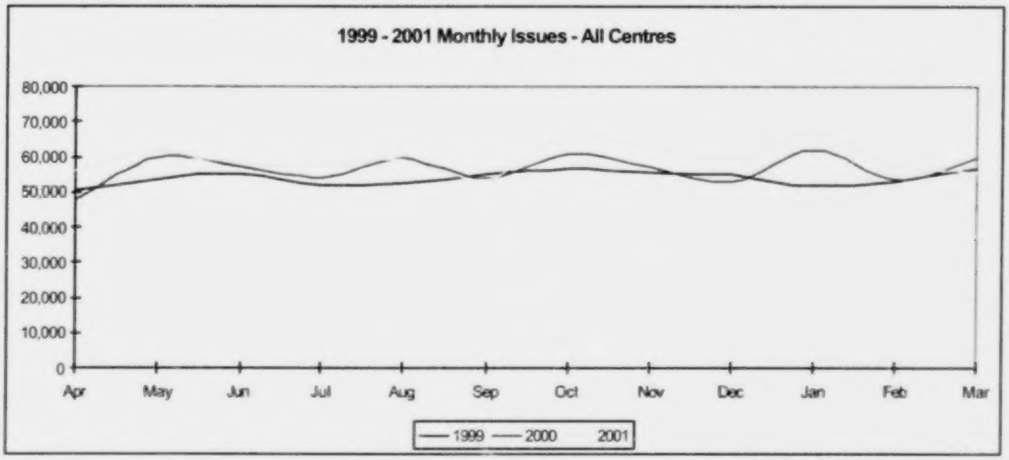
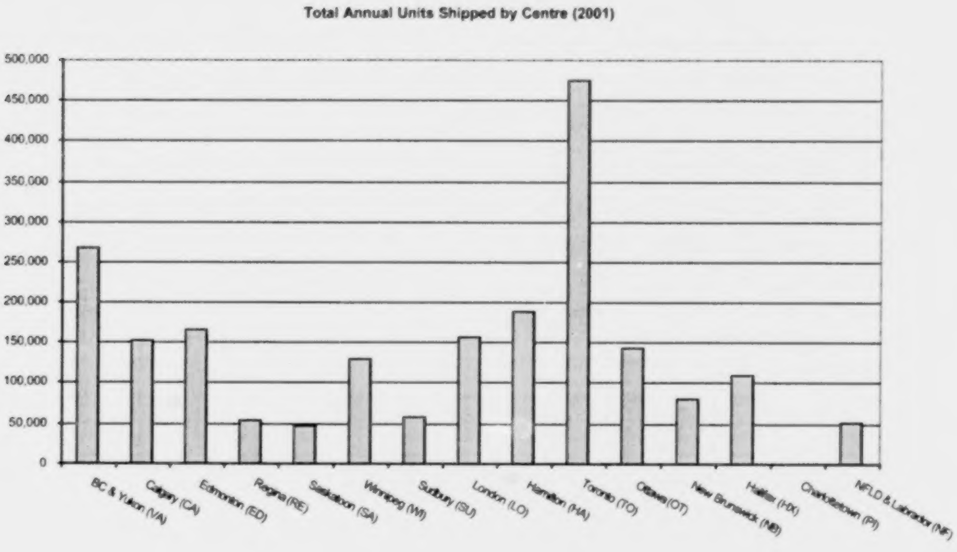


Exhibit 5-9: 1999 – 2001 Monthly Issues



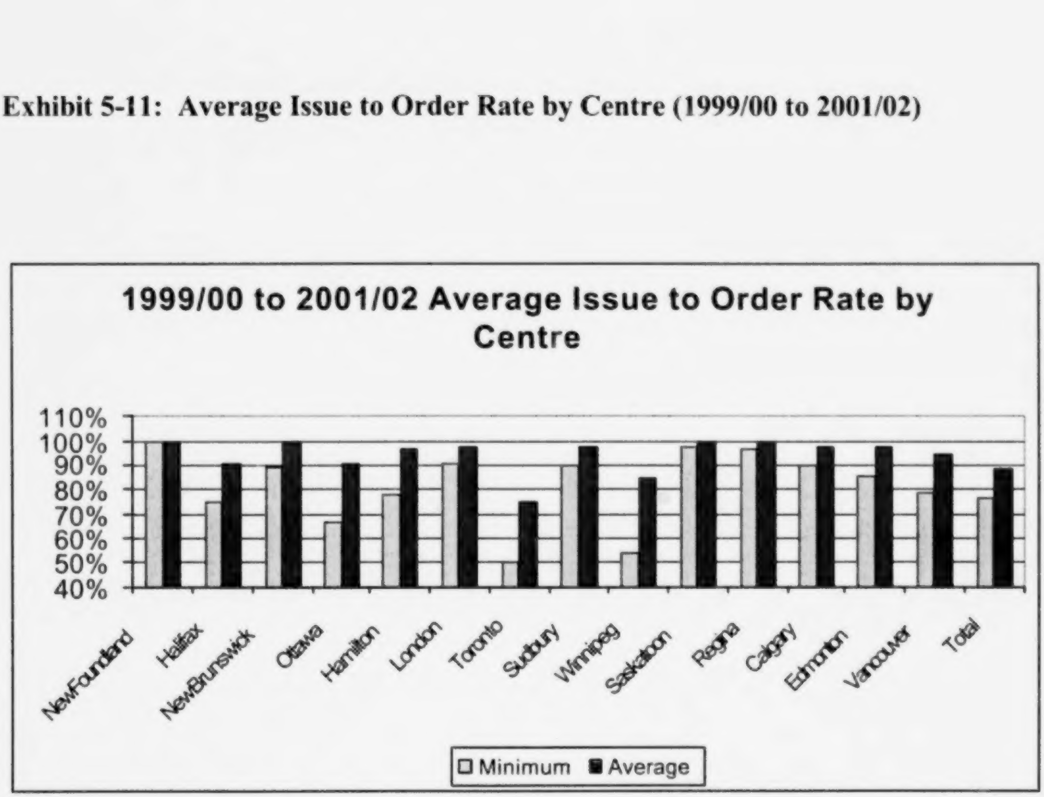
The number and type of hospitals served varies by Centre as does the volume of blood shipped. The graph below shows the 2001/02 hospital shipment volumes by Centre.

Exhibit 5-10: Total Annual Units Shipped by Centre (2001)



The ability to meet hospital demand also varies across Centres as demonstrated in the graph below. This graph shows the minimum and average issue to order ratio for each Centre over the past three years. The lowest rates were experienced by Toronto, Winnipeg, Ottawa and Halifax. The highest rates were experienced by Newfoundland, Regina and Saskatoon which were able to meet all hospital orders.

Exhibit 5-11: Average Issue to Order Rate by Centre (1999/00 to 2001/02)



The ability to meet hospital orders is one of the performance measures that CBS tracks. Last fall, CBS established a target of meeting 95% of hospital red blood cell orders, 9 out of 12 months of the year. This target was not achieved in the last fiscal year. In 2001/02, CBS met 95% of hospital orders only 5 out of 12 months of the year.

There was consensus among the Expert Panel for this review that this target is not ambitious enough. Given that the ability to supply blood to meet patient needs is the primary objective of the organization, the target should be to meet 100% of hospital orders, every month of the year.

The platelet issue to order ratio has been 94% each year for the past three years. CBS has not established a performance measurement target for platelet issues. However, the Expert Panel felt that 94% was an appropriate rate for platelets.

To supplement the analysis of CBS statistics, the hospital survey was also used to gather information on adequacy. A summary of the results is provided below and more detailed results, including breakdowns by province and hospital size, are provided in **Appendix F.**

Adequacy of Type "O" Blood Orders

The demand for blood products differs by the blood type of the product. The hospital survey asked hospitals about the adequacy of supply of Type "O" blood. Type "O" blood that is Rh+, is the most prevalent blood group in the Canadian population (38%), therefore, a high proportion of donors would have this blood type. Type "O" blood that is Rh- is much less common in the Canadian population (7%). However, the red blood cells of type O- blood donors are compatible with recipients ofall other blood types. Individuals that have O- blood are considered "universal donors".

In the hospital survey, the majority of hospitals (64%) reported that on average they received their full order of Type "O" group blood (Rh+) 96 to 100% of the time. Thirteen percent received their full orders on average between 91 and 95% of the time, while only two percent reported receiving their full orders on average less than 80% of the time. A total of 188 hospitals responded to this question.

With respect to Type "O" group blood (Rh-), 34% of hospitals reported that on average they received their full order 96 to 100% of the time, while another 20% reported receiving their full order on average 90 to 95% of the time. Thirteen percent of hospitals reported receiving their full orders on average less than 80% of the time. A total of 82 hospitals responded to this question.

Cancellation of Elective Surgeries

Industry experts have identified the cancellation of elective surgeries as an important indicator of the adequacy of a blood system. In the hospital survey, respondents were asked how many elective surgeries requiring blood components are cancelled annually as a direct result of a blood product shortage. Respondents were asked to provide data for as many years as they have readily available. Responses were as follows:

Exhibit 5-12: Cancelled Elective Surgies

Year	**Number of elective surgeries cancelled as a percentage of respondents**					
	None	**1-3**	**4-7**	**8-11**	**12+**	**No Response**
Fiscal Year 2002 (April to June)	111	2	1	1	0	106
Fiscal Year 2001	91	5	5	4	0	117
Fiscal Year 2000	88	5	2	4	1	112

It is noteworthy that a large proportion (roughly half) of hospitals did not answer this question. This is likely because the data is not routinely collected and there is no requirement to report such data to CBS or other parties.

Of the 115 hospitals that responded to this question, 3.5% of them reported that they had to cancel elective surgery at least once during fiscal year 2002 because of a shortage of blood. One of the hospitals had to cancel surgery between eight and eleven times.

Fewer hospitals reported cancelling any elective surgeries in 2002 (2%) than in 2001 (6%) and 2000 (5%). The response rate for years prior to 2000 is too low to extract any useful analysis. This means it is difficult to make an accurate trend analysis as to whether the situation is getting better or worse.

Reduction of platelet orders allocated to transfusion patients

Another indicator of how well the blood system is meeting the needs of hospitals is the frequency of reduced platelet orders. Hospital respondents were asked to indicate approximately how many platelet orders allocated to transfusion patients are reduced on an annual basis as a direct result of a blood component shortage.

Exhibit 5-13: Reduced Platelet Orders

Year	**Number of platelet orders allocated to transfusion patients reduced as a direct result of blood component shortages**					
	None	**1-3**	**4-7**	**8-11**	**12+**	**No Response**
Fiscal Year 2002 (April to June)	95	6	4	3	2	111
Fiscal Year 2001	78	7	5	1	3	121
Fiscal Year 2000	73	11	1	1	2	129

The results indicate that the number of hospitals having to reduce platelet orders allocated to transfusion patients as a direct result of blood component shortages remained constant between 2000 and 2002, being 7% for each of these fiscal years. Less than half of the hospitals that responded to the survey answered this question. This is likely because they do not track this data.

Lead Times

Eighty-three percent of hospitals reported that order lead times meet their requirements.

Most important factors when determining hospital target inventory levels

The hospital survey asked respondents questions concerning their blood service requirements, the frequency of their orders and how they communicate orders to CBS.

In summary, the factor most often ranked as the most important in establishing target inventory levels for red blood cells and plasma is historical utilization. For platelets the factor most often ranked as the most important in establishing inventory levels is the number of regular patients with medical conditions who require the regular use of these components. Approximately half of the hospitals also order blood components daily or two to three times per week with the majority (75%) ordering by phone or fax.

Respondents were asked to rank in order of importance those factors considered when determining hospital target inventory levels for key blood components. With respect to red blood cells, the responses revealed three major factors that determine hospitals' target inventory for key blood products, namely, historical usage (39% of respondents said it was the most important factor), the number of regular patients with medical conditions who require the regular use of blood products (32% of respondents said it was the most important factor), and the number of elective procedures (7% of respondents said it was the most important factor). A number of hospitals indicated that the requirement for emergency supplies was also important in determining their target inventory levels.

For plasma, the same results were noted (34% for historical utilization, 22% for the number of regular patients with medical conditions who require the regular use of blood products, and 5% for the number of elective procedures).

For platelets, however, the number of regular patients with medical conditions who require the regular use of blood products played a much greater role than historical utilization (45% of respondents indicated that this was the most important determining factor). A number of hospitals also noted that they did not keep inventory of platelets but ordered them as required.

Of the total hospitals in the survey, only 10% indicated that they would over order blood components when blood is in short supply to ensure receiving required quantities. The majority (86%) do not order more than needed to ensure receiving required quantities. A total of 212 hospitals responded to this question.

Recommendation #83: Hospitals and physicians are CBS' customers and the only links to the recipients of blood components and products. Currently, CBS' mandate ends at the hospital door and so does its access to knowledge. It is recommended that CBS shift its knowledge boundary in order to increase its knowledge of what happens to blood components and products after they are received by hospitals. The following specific strategies should be considered:

- Developing a list of hospital-based performance indicators that would allow CBS to assess the adequacy of the blood supply system. These measures should include:
    - the number of elective surgery cancellations due to blood shortages
    - the number of platelet reductions due to blood shortages
    - the number of blood transfusions
    - the number of adverse reactions to blood products
    - the discard rate for specific blood components and blood products (both

indate and outdate)
    - the volume and type of blood components and blood products shipped to, or received from, other hospitals
    - inventory levels in the hospitals
- Developing electronic linkages between the proposed MAK system and the hospitals that would permit true "vein to vein" tracking of products and information. There are cost implications to this recommendation that would need to be identified and considered in light of benefits, risks and the resources available to the Members.

5.2.2.2 Adequacy of Fractionated Products

As discussed in the financial review section of this report, the demand for fractionated products has been increasing at a significant rate. This is a global trend. The fractionation market is very volatile and product shortages are not uncommon. For the patients that depend on these products, shortages can have serious consequences. This section will focus on the mechanisms that CBS has put in place to mitigate against this risk.

CBS keeps an average of 11 weeks of fractionated product inventory on hand. This includes inventory stored at the fractionation warehouse in Ottawa and inventory at the individual Centres. Each Centre keeps approximately two to three weeks of fractionated product inventory on hand.

The determination of inventory levels for fractionated products was based on consideration of a variety of risk factors. Each risk factor has been rated by CBS as to its importance with a value of 3 for high, 2 for medium and 1 for low. The risk factors used and their ratings are as follows:

Exhibit 5-14: Risk Factors for Determining Inventory Levels for Fractionated Products[37]

Risk Factor	Relative Importance Rating out of 3
Likelihood of production failures	3
Confidence in suppliers' ability to meet forecasted requirements	1
Availability of alternate sizes of product	2
Availability of alternate products (for treatment)	3
Availability of Alternate Suppliers	3
Requirement of Specialty Raw Material for Production	1
Likelihood of Recall/Withdrawal	3
Criticality of Product	3
Ability to Forecast Demand (Variability of Demand)	*See note below

**Note:* An additional amount is added to account for variability of demand. If the analysis yields a level of 10 weeks and the average variability of demand for a product is 20%, then an additional two-week supply is needed to account for this variability. The variability was calculated using issues of products over the last two years.*

Each product group is then looked at to determine the impact of the risk factor on the product. A risk level of high, medium, or low is assigned to that factor. The scoring is the same as for the risk factors (i.e. high-3, medium-2, low-1). The rating of each factor for the product group is multiplied by the risk level score, the sum of these multiplications provides the base score for the product group. An assignment of 5 points = 1 week of inventory was applied to the analysis. The lowest score that can be obtained by the scoring system is 19 points. This corresponds to an inventory level of about one month.

CBS has a Fractionated Product Management System (FPMS) that allows them to monitor inventory use by each Centre and replenish volumes. CBS issues a "Bi-weekly Fractionated Products Update" to all of the Centres and hospitals. The report describes current inventory levels and identifies "existing and evolving inventory issues" such as potential shortages and products at risk of outdating. A copy of the bi-weekly inventory report is also sent to Health Canada. Health Canada inspects all shipments of fractionated products into the country. By keeping Health Canada abreast of inventory levels, it is hoped that inspections will be expedited quickly when there are impending shortages and shipments are urgently needed.

Hospital survey respondents were asked their level of customer satisfaction with regard to the acquisition of fractionated products. Responses were on a likert scale ranging from very good to very poor. The majority of respondents indicated that they were satisfied, with 38% reporting their level of satisfaction to be very good and 42% reporting it to be good. Only 2% of respondents indicated that their level of satisfaction was poor. Five percent of respondents did not know. A total of 208 respondents gave an answer to this question.

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[37] "Determination of Inventory Levels for Fractionation Products (Based on Forecast Annual Volumes and Current Prices as at November 1996)

Last year there was a prolonged shortage of Recombincant Factor VIII. To ensure that the crisis was managed, the CEO of CBS initiated bi-weekly conference calls involving key stakeholders – Bayer (the supplier), hemophiliacs (the users), physicians that treat hemophiliacs, Health Canada (the regulator) and CBS.

Supplier management is also important for ensuring an adequate supply of fractionated products. The majority of fractionated products are purchased from one supplier – Bayer. Some products are also purchased from Baxter and the occasional other supplier.

The continued ability of CBS to meet the rapidly growing demand for fractionated products is a major challenge to be addressed. The demand is driven by physician practices and preferences. The importance of utilization management to the sustainability of the blood system will be discussed in section 5.2.9 in relation to Cost-Effectiveness ad Cost-Efficiency.

Emergency Preparedness

Emergency preparedness is an important aspect of ensuring the adequacy and security of the blood system. Each Centre has a Service Interruption Recovery Plan (SIRP). The SIRP includes plans to address a variety of possible emergency situations including:

- Emergency and Uninterrupted Power Plan
- Inventory Management Plan (when normal operations are disrupted)
- Plan to establish an Off-Site Operations Centre
- Building Security Plan
- Management of Emergencies at Remote Locations
- Evacuation Plan
- Bomb Threat Response Plan

SIRPs for two Centres (Ottawa and Toronto) were reviewed. Both plans are detailed, reasonable and well-conceived. The strike plans were particularly impressive.

According to CBS, each Centre should review and test out its SIRP on an annual basis. There was no evidence of a recent test (i.e. mock disaster scenario) having taken place at either of the Centres for which plans were reviewed.

CBS had a service interruption in Hamilton due to a labour dispute. CBS reports that they were able to meet the need of hospital customers during the interruption.

CBS has indicated that they are currently reviewing their emergency preparedness plans on a regional and national basis in light of the lessons learned with the Hamilton situation and the September 11, 2001 crisis when most CBS Blood Centres were overwhelmed with donors.

The senior leadership team at CBS also has a role to play in emergency preparedness. An Executive On-Call Manual has been developed as a resource for use in emergency situations. The comprehensive of this manual would be improved with the inclusion of home telephone numbers for all Centre Directors.

Recently, CBS surveyed a variety of community partners (e.g. health care organizations, police, fire, ambulance services) to determine what each community partner's role would be in a local disaster.

Contingency Fund

Under the MOU, the CBS Board of Directors can set up a contingency fund for emergencies. According to the MOU, the plan for the contingency fund must be approved by the Corporate Members. The MOU authorizes CBS' Chief Executive Officer to make timely decisions, on the advice of the Scientific Advisory Committee, concerning the expenditure of funds for emergency safety response. Significant emergency expenditures are to be reported to the Members.

The contingency fund is a mechanism for ensuring the security of the blood supply because it gives CBS the ability to respond quickly to emergency issues. However, there are a number of unanswered questions about the fund including:

- How large should the fund be?
- When funds are used, how are they replenished?
- What is the definition of an "emergency"?

There is a need to address these questions to ensure accountability.

(The contingency fund is described in more detail in chapter 3 – Financial Review.)

5.2.3 A national blood supply program should be maintained.

The importance of having a national blood system was highlighted in the Krever Report:

During the 1970s and 1980s, the Red Cross encountered a shortage of donors in some provinces. Because every provincial government paid the Red Cross for operating the blood program in its jurisdiction, the governments discouraged regular, non-emergency, inter-provincial transfers of blood components. As a result, there was a *chronic shortage of blood components in some urban centres in these two decades. If the Red Cross had been encouraged to operate a truly national system, one in which blood donations were treated as a national resource and provincial boundaries were not barriers to the rational distribution of blood components, it could have eliminated the shortage of blood components and the disincentive to introduce risk-reduction measures.*[38]

CBS has made significant strides in the development of a functional, national model. Features of the current system that characterize a national model include:

- Blood is collected in all jurisdictions served by CBS except the territories.
- Blood is freely and regularly imported/exported to different provinces. In some cases agreements exist between Centres that are net importers of blood and Centres that are net exporters of blood. Information on the daily blood component inventory at each Centre can be viewed by all Centres on a lotus notes database.
- The Corporate Members and the CBS Board include representatives from all regions of the country.
- National regulations are intended to drive operational procedures.
- CBS Head Office develops Standard Operating Procedures (SOPs) and the corresponding training programs which are then disseminated to the 14 Centres.
- A number of support functions are centralized at the national Head Office level including: information technology, payroll, purchasing and marketing
- National strategies are developed by head office with input from the Centres, for example, there is a national Donor Management and Recruitment Strategy.
- Communications and marketing (including publications) are handled by Head Office to ensure promotion of a consistent brand image and to allow Centres to focus on operations.
- Plans are in place for consolidation of a number of functions including testing, manufacturing and telerecruitment.

To preserve and enhance the national model, the degree of variation among the Centres must be addressed. There are significant variations in the services provided by the Centres. Some of these variations are planned (e.g. consolidation initiatives) but others exist primarily for historical reasons. The prime example is Patient Services. There are also variations in the nature of the facilities and the equipment. Another issue that may pose a potential threat to the concept of a "national" model is the existence of a large number of Centre Operating Procedures (COPs). The number of COPs varies by Centre, but figures in the range of 180 to 750 COPs per Centre have been reported. This topic was discussed in more detail in section 2.3.4.

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[38] Krever Commission Report, Volume 3.

5.2.4 A fully integrated approach is essential.

It was not possible to assess CBS performance in relation to this principle because the meaning of the principle is very unclear. Many stakeholders made this observation. A variety of interpretations of "integration" were put forward during the course of the review including:

- Integration of blood operations, fractionation and unrelated bone marrow donor registry under one organizational umbrella
- Integration of decision-making for safety and costs
- Integration of information from donor to recipient (vein-to-vein)
- Integration of CBS with provincial health care systems

There is a need to clarify the definition of this principle either through policy or as part of a review of the Memorandum of Understanding.

5.2.5 National self-sufficiency in blood and plasma collections should be encouraged.

Canada is self-sufficient in red blood cell collections and platelet collections. We are not self-sufficient in plasma collections. In other words, CBS does not collect enough plasma to ship for fractionation. Plasma collections represent less than 30% of the nation's requirements. As a result, some plasma has to be purchased from other countries to generate the plasma-derived fractionated products that Canadians require.

Currently, there are two approaches to the collection of plasma:

- Whole blood is collected from donors and plasma is separated from the whole blood using a centrifugation process. This is called recovered plasma (RP).
- Using a technique called plasmapheresis, whole blood is removed from donors, the plasma is extracted and the remaining blood components are returned to the donor. Since the red blood cells are returned to the donor, plasmapheresis donors can donate more often (once per week to a maximum of 26 times per year compared to every 56 days for whole blood donors) because reduced hemoglobin is not a concern. However, the collections process takes longer (one hour compared to 15 minutes).

Plasmapheresis is done at some of the regional Blood Centres. There were also two Plasma Centres in Canada designated specifically for plasmapheresis. These Centres are in Thunder Bay, Ontario and Charlottetown, Prince Edward Island. Recently, the decision was made to reintroduce whole blood collections at the Charlottetown Centre in addition to plasma collections. Thunder Bay has a population of 109,000 and

Charlottetown has a population o 32,000[39]. Given the size of these communities, questions have been raised about the location of the plasma centres in relation to critical mass and viability.

Recommendation #84: The plasma centres are located in relatively small communities. Development of a plan for plasma self-sufficiency should include an assessment of the most cost-effective locations for plasma centres.

A number of initiatives have been explored over the years to address the plasma self-sufficiency issue. At one stage, CBS was considering a joint venture with a private commercial partner that would see 18 new plasma centres being built in Canada. This venture did not proceed and there have been no other initiatives pursued since. A comprehensive business case has been developed which describes a number of options. The CBS 2002-2005 Corporate Business Plan indicates that CBS intends to pursue a plan for plasma self-sufficiency but details of the plan have not yet been developed. The information required to support a policy debate on this issue is currently lacking in the following areas:

- Clear delineation of plasma collection costs (including recovered plasma) is still under development.
- There is a lack of guidelines on the utilization of fractionated products which will determine the appropriate level of demand for which to plan.

5.2.6 Accountabilities must be clear.

CBS is accountable to its Corporate Members (the Provincial/Territorial Members). The roles and responsibilities are set out in a Memorandum of Understanding that is discussed in more detail in the Governance and Risk Management chapters of this report. The CBS Board is accountable for carrying out the functions described in the MOU. The main tool for accountability is the multi-year budget process. Each year, CBS submits a one year budget and a three-year corporate plan to the Members for approval.

As noted in section 2.3, accountabilities are not completely clear. There are ambiguities in the MOU and a lack of consistent understanding of the roles of the Corporate Members and the CBS. This is a critical issue that will require close attention in the coming years.

CBS is also accountable to Health Canada on quality and safety issues. CBS must comply with regulations set out by Health Canada or risk losing their license to operate.

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[39] Statistics Canada 2001 Population and Dwelling Counts

They must permit Health Canada to audit their facilities. And, there are certain incidents/events that must be reported to Health Canada.

There is also an expectation that CBS will be accountable to the public. CBS' performance in this area is described in section 5.2.8 below under the principle of transparency.

5.2.7 The system must be transparent.

The importance of openness and transparency to stakeholders following the tainted blood crisis cannot be understated. Over its four-year history, CBS has struggled to meet this goal. Some strategies have been successful and other strategies have had to be re-designed.

On March 10, 2000 the Board of Directors of CBS announced the establishment of a three-member 'Public Participation Task Force". The purpose of the Task Force, as articulated by the then-Chairman of the Board, was to provide the Board with advice on "operating in an open and accessible manner and to ensure public participation in decision-making."[40] The terms of reference for the Task Force were to:

1. Review the kind of decisions required by CBS and make recommendations on
    - The kind of decisions to which the public and the stakeholders should participate
    - The degree of this participation
    - The identification of the different publics (inside and outside stakeholders) to be involved in CBS decision-making
    - The criteria by which achieving a satisfactory public participation will be assessed
2. Take into account existing practices and models of public participation and make recommendations on
    - The most appropriate processes and structures to involve stakeholders (inside and outside) and the general public in CBS decision making
    - Any modification they may see as required to the CBS governance model[41]

The final report of the Task Force was submitted in November 2000. It identified the strengths and weaknesses of the CBS in relation to public participation. The report acknowledged the commitment of the Board to addressing this issue:

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[40] "Final Report of the Task Force on Public Participation to the Board of Directors of Canadian Blood Services", November 2000, page 3.

[41] "Public Participation Task Force – CBS, the Blood System and Public Participation: An Overview", prepared by CBS, April 14, 2000, page 3.

"We were also impressed with the fact that, as an organization which inherited its mandate under difficult circumstances, Canadian Blood Services has been preoccupied with issues about openness, transparency, and availability of information for the public throughout its brief existence."[42]

One of the key concerns raised by the Task Force was the ineffectiveness of the "Consumer Advisory Committee" that was in place at the time. The Krever Report had recommended the creation of a "liaison committee, consisting of representatives of community and consumer organizations".[43] Krever recommended that this committee report to the CBS Board. However, CBS chose a different approach and created a "Consumer Advisory Committee" that reported to the Chief Executive Officer rather than the Board. The MOU provides CBS with the option of having this Committee report to either the CEO or the Board. This structure was not well-received by consumer stakeholders.

CBS has since abandoned the Consumer Advisory Committee in favour of a National Liaison Committee that does indeed report directly to the Board of Directors. The Committee is co-chaired by the two consumer representatives on the Board. Over a dozen consumer associations are represented on the membership of the Committee.

Some of the other strategies that CBS has implemented to improve openness and transparency to the public include:

- Two open board meetings per year
- Publication of board minutes on the CBS website
- Publication of Health Canada audit results on the CBS website
- Consultation with consumer associations on relevant policy issues (e.g. donor deferral)
- Public forums
- Preparing a policy on access to information
- Involvement of consumer associations in a recent Request for Proposal process for fractionation services
- Publication of newsletters such as "Bloodbeat" and "Inside Circulation"
- Regular public surveys

Most of the stakeholders consulted for this review felt that transparency has improved over the years. The consumer associations interviewed were generally satisfied with the degree of transparency.

One stakeholder pointed out the important difference between transparency and public relations. With a "public relations" model, the decision about what type of information to share with the public is made by the organization. Under a truly "transparent" model, the public will also have the opportunity to determine what information is shared through mechanisms to respond to public requests for information. If these models can be positioned on a continuum along which an organization progresses, CBS is performing well from a public relations perspective but there is still room for improvement to be considered truly transparent to all stakeholders. Board members acknowledge that they are still struggling with what transparency means and how best to achieve it.

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[42] Final Report of the Task Force on Public Participation to the Board of Directors of Canadian Blood Services", November 2000, page 14.

[43] Krever Report, Recommendation 14, page 1055.

CBS treats the need for Transparency as a journey, not a destination and through a variety of mechanisms, work hard at ensuring the public is kept aware of what is happening at CBS. In fact, two consumer group representatives rated CBS high on communications. While they felt the need for frequent communications had diminished with the introduction of a safe blood system, they felt comfortable picking up the phone and contacting the current CEO should a concern arise.

5.2.8 A cost-effective and cost-efficient blood supply program for Canadians should be encouraged.

A variety of indicators were examined to assess the extent to which CBS has achieved a cost-effective and cost-efficient blood supply program. The indicators that will be discussed in this section are:

- Unit costs
- Labour hours per unit
- Overhead costs
- Discard rates
- Impact of new programs and processes
- Impact of the rising demand for fractionated products
- CBS initiatives to improve cost-effectiveness and cost-efficiency.

Where possible, international benchmarking results have been included.

5.2.8.1 Unit costs

The cost of producing a unit of product is an indicator of cost-effectiveness. CBS tracks a performance measure that they refer to as "cost per red blood cell". This measure is somewhat misleading given the formula used. For performance measurement purposes, CBS calculates the cost per red blood cell as follows: Total Blood Operations (excluding Captive Insurance and Fractionated Products) divided by the number of red blood cells issued. Since whole blood is divided into a number of products (red blood cells, plasma and platelets) it is inaccurate to attribute the total blood operations costs to red blood cell production. However, component unit costs are currently not calculated by the CBS. The current formula puts the cost per red blood cell at $467. CBS established a target to reduce the cost per unit by 5% by the end of fiscal year 2001/02. This target was not achieved.

CBS is encouraged to develop a more meaningful cost per unit indicator such as the one proposed in Chapter 3.

By comparison, in the U.S. where a different funding structure applies, blood centres have lists of "service fees" for each type of blood component produced. For example, for a group of blood Centres called "America's Blood Centers" the average service fee for leukoreduced red blood cells was $143 US ($219 CDN) per unit in 2001. The average service fee for leukoreduced apheresis platelets was $514 US ($787 CDN) in 2001. It might be beneficial for CBS to inquire about the costing methodologies used at these Blood Centres.

5.2.8.2 Labour hours per unit

CBS tracks total whole blood collection hours divided by the total whole blood collections. The current target is to achieve 1.82 hours per whole blood collection by March 31, 2003. For fiscal year 2001/02, seven of the Centres were below the targeted hours. The national average for 2001/02 was 1.98 with a range from 1.49 (Calgary) to 2.40 (Ottawa).

CBS also tracks the total Component Production hours divided by the total whole blood collections. The current target is 0.41 hours by March 31, 2003. For the fiscal year 2001/02, seven of the Centres were below the targeted hours. The national average for 2001/02 was 0.50 with a range from 0.37 (Halifax) to 0.72 (Newfoundland).

Through the international benchmarking survey, some limited data on labour hours per function has been obtained. It is summarized in the table below:

Exhibit 5-15: International Comparison of Labour Hours Per Collections, By Functional Area

Labour Hours For Functional Areas	CBS	Hema-Quebec	Sweden	U.K.	U.S.
Labour Hours for Donor Recruitment per Total Units of Whole Blood Collected	1.065	0.115	N/A	0.248	N/A
Labour Hours for Whole Blood Collection per Total Units of Whole Blood Collected	2.265	3.208	N/A	1.410	N/A
Labour Hours for Plasmapheresis Collection per Total Units of Plasma Collected	2.113	2.825	N/A	N/A	N/A
Labour Hours for Cytapheresis Collection per Total Units of Platelets Collected	3.890	2.950	N/A	2.675	N/A
Labour Hours for Manufacturing/Processing per Total Units of Whole Blood Collected	0.554	0.997	N/A	0.329	N/A
Labour Hours for Blood Testing per Total Units of Whole Blood Collected	0.900	0.432	N/A	0.184	N/A
Labour Hours for Storage and Distribution per Total Units of Whole Blood Collected	0.732	0.961	N/A	0.304	N/A
Labour Hours for Quality assurance and Quality Control per Total Units of Whole Blood Collected	0.407	0.245	N/A	0.036	N/A
Labour Hours for Administration/Overhead - National Level per Total Units of Whole Blood Collected	0.741	0.483	N/A	N/A	N/A
Labour Hours for Administration/Overhead - for all Regional Blood Centres per Total Units of Whole Blood Collected	0.889	N/A	N/A	0.131	N/A
Labour Hours for Other per Total Units of Whole Blood Collected	0.985	1.198	N/A	0.649	N/A
Total Labour Hours per Total Units of Whole Blood Collected	8.560	7.790	3.726	3.397	N/A

The results above exclude fractionated product and UBMDR labour hours. They indicate that CBS has a higher labour hours per collection rate than the comparator countries in the areas of donor recruitment, testing, quality assurance and administration/overhead. It is important to note that Hema-Quebec currently outsources NAT-testing so they would not be reporting any labour hours for this function.

When the total labour hours per whole blood units collected is compared with three other jurisdictions, CBS has the highest result. It is noteworthy that both CBS and Hema-Quebec have significantly higher labour hours per whole blood unit than Sweden and U.K. Although, labour hours statistics were not provided on the survey submitted by the American Red Cross, U.S. blood system experts report that total labour hours per unit is approximately 3.4. This figure is in keeping with the data reported by Sweden and the U.K.

Recommendation #85: Total labour hours per collection at CBS is much higher than in the countries that participated in the international benchmarking survey. It is recommended that CBS continue to benchmark this indicator with other systems and identify reasons for the variance and opportunities for efficiencies based on practices in other jurisdictions.

Recommendation #86: It is recommended that CBS conduct assessments of the costs, benefits and risks of various collection centres, clinic models and alternative collection processes (e.g. Bloodmobile) in order to focus future investment on the most cost-effective collection methods.

Data was also collected on the ratio of volunteer labour hours to staff labour hours for CBS and Hema-Quebec. The findings show a ratio of 0.04 volunteer hours per paid staff labour hour for CBS compared to a 0.14 for Hema-Quebec. It would be informative for CBS to learn more about Hema-Quebec's volunteer strategy.

5.2.8.3 Overhead costs

It is generally recognized that organizations are more cost-effective when overhead costs are minimized. At CBS, administrative overhead (for head office and the Centres) accounted for 24.1% of blood operating expenditures in 2000/01 and 22.8% in 2001/02.

The consulting team and the Expert Panel for this review were in agreement that this proportion of overhead is higher than expected. By comparison, the Expert Panel estimates the overhead rates at U.S. Blood Centres to be 14 to 15% on average. Also, based on the international benchmarking survey, Hema-Quebec has an overhead rate of approximately 12% of total blood operating costs. Ontario hospitals spend an average of 8.9% of operating dollars on "corporate " or administrative services.

The overhead for the fractionated products part of the organization was 0.5% in 2000/01 and 1.2% in 2001/02. The increase in dollars from one year to the next was significant – from $1.6 million to $5.2 million. CBS management identified three factors to explain the variance:

- Recording of a write-off for the donation of a surplus of plasma-derived Factor VIII to third world countries when the shortage of Recombinant Factor VIII ended
- Increased resources required to manage the Request for Proposals for Fractionated Products
- Reallocation of costs from another cost centre

Another issue is the need for improved consistency in the definition of administration and overhead costs. Over the years, there have been changes in how cost items are accounted for. This is also a limitation for benchmarking with other organizations because of variations in what is considered administration/overhead.

5.2.8.4 Discard rates

Discard rates are a measure of the degree of waste within the system. The more waste there is, the less cost-effective and cost-efficient the system is. Discards can include product that is disposed of because it has passed its shelf-life or expiry date. This is referred to as the "outdate rate". Sometimes discards occur for other reasons such as improper packaging, poor temperature control, etc. Both types of discards can occur in the Blood Centre or at the hospital. Each one is discussed below:

Centre Discard Rates

CBS tracks three types of discard rates as part of its operational performance measures:

- whole blood and red blood cell concentrates
- platelets, leukocytes reduced by filtration (LRF); i.e. platelets derived from whole blood collections
- platelets collected through apheresis

For whole blood and red blood cell concentrates, CBS' target is for each production site to have a discard rate of no more than 6.76%. For the fiscal year 2001/02, only one of the 14 sites was below the target rate. The national average discard rate was 8.54% and the sites ranged from 4.12% (Toronto) to 13.54% (Saskatchewan). By comparison, the American Red Cross reported a red blood cell Centre outdate rate of 1%.

Platelets are a very valuable blood component and they have a very short shelf-life. For leukoreduced platelets, the CBS target is for each production site to have a discard rate of no more than 13% by March 31, 2003. For fiscal year 2001/02, three of the 14 Centres (Toronto, Regina and Saskatchewan) were below the target rate. The national average was 18.08% and the range of discard rates was from 6.66% (Saskatchewan) to 42.69% (Newfoundland). Sudbury also had a very high platelet discard rate of 38.67%.

The target for platelets collected through apheresis is a discard rate of no more than 4% by March 31, 2003. For fiscal year 2001/02, three of the 14 Centres (Calgary, Toronto and Ottawa) were below the target rate. The national average was 6.68% and the range of discard rates was from 1.26% (Calgary) to 28.57% in New Brunswick.

The Expert Panel for this review expressed concern about the high discard rates for all blood components but especially for platelets. There was also a sense that the targets should be more aggressive (i.e. lower).

Hospital Discard Rates

Unfortunately, data on hospital discard rates is limited. Hospitals are not required to report their discards to CBS. However, some hospitals do report this data voluntarily.

According to CBS, a total of 2,615 RBC were voluntarily reported as outdates in fiscal year 2001/2002. This should be considered a minimum figure since reporting is not mandatory. Also, this figure would be more meaningful if it was reported by blood group. Information on hospital discard rates in other jurisdictions is not readily available and only one blood service agency that participated in the international benchmarking survey reported this data. The American Red Cross reports a hospital discard rate for red blood cells of 0.25% including outdates and units returned or recalled for other reasons.

The hospital survey also sought to gather data on hospital discard rates. The number of discarded units for each type of blood product is shown in the table below. Discards include units that were discarded for any reason, not just outdating. The results show that the discard (outdates) data reported to CBS only represents the "tip of the iceberg" in terms of the discard situation.

To estimate the value of the discarded units, unit costs were derived from two sources. The cost per unit for red blood cells is the same figure reported in Chapter 3 of this report. Since CBS does not report the cost per unit for other blood products, the unit cost used in this analysis is based on the price list for America's Blood Centres with the appropriate conversion to Canadian dollars. The results are shown in the table below.

Exhibit 5-16: Estimated Hospital Discard Rates and Value of Discarded Units

Product	Stored on site? (All Responses)	Estimated Total Units Shipped to Question Respondents	Estimated number of units discarded per year (As reported in survey)	Estimated % discarded (of total units shipped)	Estimated Unit Cost in $CDN	Estimated Value of Discarded Units
Red Blood Cells	*Yes:* 85% *No:* 12%	264,863	12,698	4.8	$396*	$5,028,408
Platelets	*Yes:* 14% *No:* 76%	117,046	20,856	17.8	$80**	$1,668,480
Cryoprecipitate	*Yes:* 33% *No:* 57%	14,687	1437	9.8	$64**	$91,968
Cryosupernatant	*Yes:* 5% *No:* 83%	8,161	281	3.4	N/A	N/A
Total						**$6,788,856**

**As calculated in Chapter 3 of this report*

***Based on Average Service Fee for Platelet Concentrates, America's Blood Centers, 1982-2001" converted to Canadian dollars.*

The analysis indicates that the value of the discarded units reported by hospital survey respondents is in excess of $6 million or 2% of CBS' Blood Operations budget. The estimated value of discarded platelets alone is $1.7 million. This is a conservative estimate of the cost of platelet discards because it assumes that all discards are platelet concentrates (random donor platelets) which cost approximately $80 per unit compared to the more expensive platelets collected through apheresis which costs $787 per unit. Clearly, there would be great benefit in exploring opportunities to minimize discard rates.

If these reported discard rates are applied to the entire volume of blood components shipped in 2001/02, the estimated system-wide value of discarded red blood cells, platelets and cryoprecipitate would be $16.2 million.

One of the issues that stakeholders have raised is the CBS policy not to accept blood components or products back from hospitals once they have been delivered. As a result, when hospitals know they have inventory that is at risk of becoming outdated their options are to contact other hospitals to see if they could use the units and arrange for transport of the units or to do nothing and allow the units to expire. A number of hospitals in Canada report that they do transfer blood products to other hospitals.

British Columbia has a particularly active Inter-regional Blood Redistribution Program that grew out of a need to address blood shortages. To reduce blood wastage at remote blood banks in BC, in November 1997 the Provincial Blood Coordinating Office (PBCO) initiated a project involving the redistribution of near-outdated (i.e., near expiry date) blood from low-utilization hospitals to St. Paul's Hospital in Vancouver.

A quality framework was developed, including temperature monitoring of units in transit, to ensure patient safety is not compromised. Twenty-six hospitals are now redistributing blood to St. Paul's Hospital. Six hospitals recently started redistributing blood to Vancouver General Hospital. The provincial wastage (outdate) rate has dropped from 9% (1997) to 4% (2001)[44]. The estimated annual savings from the program is $1.3 million. In the future, the program plans to analyze wastage patterns to optimize the redistribution network. A key performance target for the program is to continue to maintain a provincial blood outdate rate of 4% or lower.[45]

This has been done in other jurisdictions as well. A 1999 article entitled "Inter-regional Blood Redistribution" reported on a pilot project involving the redistribution of red blood cells between regions. The aim was to reduce blood outdating and associated costs while maintaining transfusion safety. The study found that: on an annual basis, 1,001 units of blood were saved (for 17 small hospitals), the outdate rate was improved, there was a slight increase in spoilage due to errors in packing and shipping, patient outcomes were unchanged and shipping costs equalled approximately 10% of the value of the blood saved. The study authors concluded: *"Inter-regional redistribution appears to be a cost-effective means of improving inventory management while maintaining transfusion safety."*[46]

In some countries, the Blood Centre will accept blood components and blood products returned by hospitals as long as they are assured that proper storage and transport procedures were followed. Another role that Blood Centres can play is to serve as a "broker" for the transfer of blood units among hospitals. One of the advantages of having the Blood Centres involved in this blood exchange activity, is that they can help to ensure compliance with procedures that will ensure the blood is properly tracked in the event that a lookback or traceback process is required in the future.

Hospitals were asked how they monitor the aging of blood products. A total of 207 hospitals provided a response. The majority of hospitals indicated that they (60%) monitor the aging of blood by manual methods. Only 11% of hospitals use a computerized system, while 21% use a combination of automated and manual systems.

Respondents were asked what percentage of blood products typically cannot be used because of spoilage (not including outdated or expired blood product). The majority of respondents (35% of the total population or 75% of the hospitals that responded to this question) indicated that they would typically discard less than one percent of blood products because of spoilage. One respondent noted that they would discard no blood ordered for specialities, but would discard 60% of that ordered for emergencies. Only 103 hospitals provided a response to this question.

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[44] There is a slight increase in province blood wastage rate in 2001-02 as compared to 2000-01. This is likely due to the impact of Sept. 11 event with sudden surge of blood supply that exceeded demand for several months.

[45] Provincial Blood Coordinating Office Status Report (2002-03), May 2002.

[46] "Inter-regional Blood Distribution Summary Report", Selin, S., Pi D. Canadian Society for Transfusion Medicine Bulletin, Vol. 11, No. 2, June 1999.

Recommendation #87: Discard rates are above desired levels both at Regional Centres and at hospitals (although data is limited). Based on the results of the hospital survey, the value of discarded blood components is at least $6 million and perhaps as high as $16 million. It is recommended that CBS develop strategies for Centres to use to minimize discard rates of all blood components and products. Even a 10% reduction in discards could result in savings of up to $1.6 million. Strategies should consider the work already being done in provinces such as British Columbia.

Recommendation #88: It is recommended that CBS re-evaluate their role in facilitating effective inventory management of blood and blood products throughout the blood system (including hospitals). Examples of strategies that might be considered include:

- Revisiting the policy of not accepting blood or blood products once they have been delivered to hospitals; consideration might be given to developing a formal agreement (e.g. Memorandum of Understanding or Service Level Agreement between CBS and hospitals) that would the set out the criteria under which CBS would accept indated returned products from hospitals. Criteria would address such parameters as proper storage, temperature control and transport requirements. The Australian Red Cross Blood Service is moving in this direction.
- Playing a coordinating or brokerage role in the exchange of blood components and products among hospitals. Some hospitals across the country have arrangements with other hospitals for the exchange of blood components and products to minimize discards due to outdating. Some of these arrangements are more formal than others. Given the importance of being able to accurately track the ultimate destination/recipient of blood components and products (for lookback/traceback purposes), it would be helpful for CBS to provide coordination and guidelines for the exchange of blood units among hospitals.

5.2.8.5 Impact of New Programs and Processes

There is a lot of interest in the cost impact of new programs and processes that CBS has introduced. Two initiatives in particular have been the subject of much debate: universal leukoreduction and NAT testing. Each one is discussed briefly below:

Universal leukoreduction was introduced in 1999. CBS was required by the regulator to implement leukoreduction. This new process had significant cost implications. Most notably, the cost of blood bags increased from $7 per bag to $42 per bag for a total cost impact of approximately $26.6 million. Currently, CBS has only one supplier of blood bags. Although there is recognition that some level of cost increase is required, the fact that there is a sole supplier raises questions about whether CBS is attaining the most reasonable price for the bags. Universal leukoreduction highlights the fact that the regulatory environment is a cost driver.

NAT testing for Heptatis C was introduced in 1999 and NAT testing for HIV was introduced in 2001. Implementation of these tests came at significant costs. First specially designed labs had to be constructed at the four testing sites. Then came the cost of writing the required Standard Operating Procedures and training staff. Finally, there was the cost of the test kits. The cost of the HCV-NAT test kits is $5,232. The cost of the HIV-NAT test kit is $1,679. It is important to note that each test kit is used to test numerous donors because tests are done in pools of 48. The disconcerting factor is the difference in costs between the two test kits. The difference is mainly due to a royalty fee charged on the HCV-NAT test kit because a company called Chiron holds a patent on the Hepatitis C virus. This royalty has had a significant impact on the cost of HCV-NAT worldwide. The royalty fee is charged per donor regardless of whether donations are tested individually or in pools. Royalty payments could compromise the cost-effectiveness of HCV-NAT tests.[47] In Canada, CBS has been using HCV-NAT for almost three years and only one window case has been identified. The UK had a similar experience. In the UK, one group of researchers estimates the cost per life year saved with HCV-NAT at £31.5 million ($71.5 million CDN). This is compared to £5,000 ($11,364 CDN) per quality adjusted life year for a heart transplant. Because NAT testing is expensive and the number of positive test results are very low questions have been raised about the cost-effectiveness of the test.

In the absence of a policy framework that addresses how to balance safety and costs in an environment of cost-restraint, it is not clear how the decision on whether new initiatives should be introduced or if some should be discontinued will be made.

5.2.8.6 Impact of the Rising Demand for Fractionated Products

Another factor that affects cost-effectiveness of the blood supply system is the rising demand for fractionated products. The increasing volumes and costs experienced by CBS have been discussed elsewhere in this report. To achieve cost-effectiveness in the area of fractionated products will require a variety of utilization management approaches. But utilization decisions are made by physicians perhaps with input from patients. The package inserts for fractionated products describe the indications for which fractionated products should be used. However, it was reported that many physicians are contributing to "off label usage" – using the products for conditions other than those approved by the regulatory authority. Some provinces have made significant progress in addressing this issue.

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[47] "The UK blood transfusion service: over a (patent) barrel?", The Lancet, Vol. 359, May 18, 2002, page 1714

Data collected by the Halifax Blood Centre illustrates this point. In 2001/02, expenditures on IVIG for CBS nationally exceeded $114 million – more than any other fractionated product offered by CBS. The Halifax Blood Centre in conjunction with major hospitals in Nova Scotia, gathered data on the IVIG usage in 92 patients.[48] These 92 patients had received a total of 16,766 grams of IVIG. The indications for IVIG usage and patient diagnoses were coded as either:

- Labeled (L) – Manufacturer can "advertise" the use of the product for these diagnoses
- Unlabeled But Potentially Indicated (UL-I) – Although the manufacturer cannot "advertise" the use for these diagnoses, there is evidence to support their use
- No Apparent Indication (UL-N) – There is no evidence supporting the use of these diagnoses.

The study found that 91.3% of all indications were either "labelled" or "unlabeled but potentially indicated". The remaining 8.7% were for "no apparent indication". The study also reported that information that had been gathered nationally on 1,998 patients from Alberta, Saskatchewan, Ontario, New Brunswick , PEI and Yukon found that 22% of usage was for no apparent indication. Assuming that the extent of IVIG usage for conditions that are not indicated lies somewhere within the range of 8.7% to 22%, this corresponds to costs of $9.9 million to $25 million that could be saved through improved utilization management.

These results highlight the potential for tremendous cost savings through utilization management approaches that include national clinical guidelines for IVIG usage.

As another positive example, BC's IVIG Utilization Management Program is an evidence-based approach to controlling the escalating use and cost of IVIG. Under the Program, which was developed in partnership with provincial medical specialists, the Ministry of Health Services will routinely fund IVIG prescriptions only for a specified list of conditions for which there is convincing evidence of benefit of IVIG therapy. A key provision of the program is the need for prerequisites to be met before IVIG use can be approved. This ensures that IVIG is reserved for patients who are most likely to benefit from the therapy.

An IVIG Centre has been established at the PBCO to provide educational, technical and clinical support to the hospitals, as well as data collection and analysis. In February 2002, the program entered the pilot phase at six hospitals: St. Paul's, Vancouver General, Royal Columbian, Children's and Women's, Royal Jubilee and Victoria General. Together these sites account for approximately 45% of IVIG use in BC.

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[48] "Summary of the CBS Hospital Customer Meeting – June 7, 2002", page 35.

Feedback from participating blood banks and physicians has been positive. The rollout to remaining hospitals began with an implementation workshop on May 3, 2002. It is anticipated that large IVIG users and key regional hospitals will implement the program by the end of June 2002. Smaller hospitals will be added by the end of September 2002. Future plans for the program include: continuing with the provincial rollout and support to hospitals, providing a detailed analysis of IVIG use in BC, reviewing program operation to date and discussing any necessary changes to the guidelines, collaborating with the other provincial/territorial Health Ministries and CBS in developing a national IVIG Utilization Management framework and evaluating the impact of the program and adjusting its future direction.

The performance targets for the program are:

- Stabilize IVIG use (grams per capita) over 2002-03, with a 5% decrease in 2003/04.
- Provide an analysis of categories of clinical indication of IVIG usage.
- Provide a policy analysis of options to further limit IVIG utilization.[49]

CBS has also taken steps to address the challenge of IVIG utilization. They hosted a "Consensus Conference" on IVIG in October 2000 however, the results have not yet been disseminated to stakeholders. There are no national guidelines for IVIG usage and there is a lack of clarity around who should take the leadership role (CBS or the provinces and territories) for development of such guidelines.

Many hospitals have introduced blood utilization or blood transfusion committees in order to manage utilization of blood components and blood products. In the hospital survey, 43% of respondents reported that they have such committees. Some of the provincial blood reference groups have studied fractionated product utilization in their hospitals. Utilization management of fractionated products will be critical to the sustainability and affordability of the blood system. Clearly, it is not an issue that CBS can solve on its own – it will require the collaboration of CBS, provincial/territorial health ministries, hospitals and physicians.

5.2.8.7 CBS initiatives to improve cost-effectiveness and cost-efficiency

Some of the initiatives that CBS has already introduced to improve cost-efficiency are:

- Mandatory appointment booking for donors so that clinic activity is more predictable
- A standardized clinic model
- Centralization of key support functions such as information technology, finance, payroll and purchasing

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[49] Provincial Blood Coordinating Office Status Report (2002-03), May 2002.

- Tracking of operational performance measures and comparing these metrics across the various Centres

Several further initiatives are being planned by CBS to improve cost-efficiency including:

- Enhanced automation of blood operations, for example:
  - MAK Progesa will automate many information management functions that are currently done manually
  - PRISM technology will replace traditional testing for enzyme linked immuno assay. Whereas current testing methods require 5.5 FTEs to test 810 samples per shift, PRISM automates the testing process and requires only one FTE to test 1,000 samples per shift[50]
- Consolidation of testing from 11 laboratories to three laboratories in Calgary, Toronto and Halifax. The introduction of PRISM technology will allow these consolidated sites to handle large volumes of samples in a timely manner
- A Bloodmobile pilot is underway and may potentially lead to a more cost-effective approach to blood collections
- A National Contact Centre is being planned to replace the decentralized donor telecruitment function currently in each Centre

5.2.9 Voluntary donations should be maintained and protected.

This is an important principle for some countries because there is a sense that the blood pool is safer when donations are voluntary as opposed to when there are financial incentives to donate. For instance, donors may be less honest on donor screening forms if their main motivation is to collect payment for the donation.

All blood donations to CBS are voluntary. There are over 1.9 million donors in the CBS donor database. In the 2001/02 fiscal year, 24% or 465, 555 donors in the database were active donors. Active donors are donors that have made a donation within the past 18 months. In 2001/02, there were 100,859 new donors; an increase of 13.7% over the previous year.

In terms of demographics, 50.7% of donors are males and 49.3% are females. An age breakdown of the active donor base is provided below:

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[50] Information supplied by PRISM Project Coordinator, Toronto Blood Centre, June 26, 2002.

Exhibit 5-17: Blood Donor Demographics

Age Group	Percent of Active Donors in Age Group
17 to 24	22%
25 to 34	18%
35 to 44	27%
45 to 54	22%
55 to 65	10%
> 65	1%

Note: Donors may donate from the age of 17 to 70 years. Donors over the age of 66 must have donated within the last two years. First time donors must be between 17 and 60.

The table below illustrates that the percentage of active donors varies by province and is not always equal to the proportion that the province represents of the Canadian population.

Exhibit 5-18: Donors by Province

Province	Percent of the Canadian Population (excluding Quebec)	Percent of the Active Donor Base
British Columbia	17%	12%
Alberta	13%	15%
Saskatchewan	4%	6%
Manitoba	5%	6%
Ontario	51%	48%
Nova Scotia/PEI	5%	6%
New Brunswick	3%	4%
Newfoundland	2%	3%

Note: Blood is not collected in the territories.

Nationally, 3.6% of the eligible Canadian population are active donors. This rate also varies by province as reported in section 2.3.3

The table below shows that when compared to other blood systems, Canada has a relatively low rate of donors per population. These figures are based on the percentage of donors for the total population rather than the eligible population because different countries have different donor eligibility criteria.

Exhibit 5-19: International Comparisons of Percent Donors Per Total Population

CBS	Hema-Quebec	Sweden	U.K.	U.S.
1.71%	2.10%	3.19%	3.75%	1.46%

Although a lower percentage of Canadians donate blood, the table below shows that the average number of donations per donor in Canada is slightly higher than in the comparator countries.

Exhibit 5-20: International Comparison of Average Donations Per Donor

CBS	Hema-Quebec	Sweden	U.K.	U.S.
2.0	1.5	1.8	1.3	1.6

To maintain and protect voluntary donations, CBS has introduced a number of programs and initiatives including the donor for life program, programs geared to high school students, holiday campaigns and special promotions. Over 1,300 staff that deal with donors participated in a Customer Service Excellence training program. In conjunction with this program, a customer service awareness program was developed. CBS also regularly monitors donor satisfaction with the donation process. Donor input is collected through comment cards handed out at the clinics. In May 2001, CBS established a 5,000 member Donor Advisory Panel that it surveys on a regular basis on such issues as marketing, communications, customer service and policy initiatives. There is also a Mystery Donor program whereby selected donors are engaged to play an inspection role when they visit their clinic and gather specific information that is then reported to CBS. Recent surveys suggest that the majority of donors have a high degree of satisfaction with the donation process.

The most common complaints about the donation process relate to turnaround time and convenience. CBS has introduced a number of initiatives to address these issues including:

- Appointment bookings for donors
- Opening of two new permanent clinics
- A Bloodmobile pilot in Ottawa
- A Life Bus program to transport employees from their workplace to clinics
- A national toll-free line (1-888-DONATE) that provides information about donating

Enhancing the donor base is a key strategic priority for CBS. They have established a target to increase the proportion of active donors from 3.6% of the eligible population to 5%. According to CBS, this increase is required to keep pace with the growing demand for blood components.

Recommendation #89: The results of the last Census show that Canada's ethnocultural population is growing and the nation is becoming more diverse in terms of culture and language. Given the need for CBS to increase its donor base to keep pace with growing demand, it is recommended that CBS identify ways to enhance responsiveness to Canada's growing multicultural community. Strategies considered should include:

- Allowing for translation and interpretation support in the donor screening process
- Multi-lingual advertising in the ethnocultural media
- Multi-lingual educational materials about blood donation
- Targeted recruitment of volunteers from ethnocultural communities
- Holding clinics in communities with high ethnocultural populations
- Establishing a multicultural advisory committee to advise CBS on the most

effective ways to increase donations from multicultural communities

- Promoting the innovative practices that some of the Centres have adopted (e.g. one Centre organized clinics for the Muslim community with separate donation times for men and women or curtains to separate the male donors from the female donors).

5.2.10 Gratuity of all blood, components and plasma fractions to recipients within the insured health services of Canada should be maintained.

Currently blood is free to all recipients that are covered by Canada's health insurance program.

It is important to note that blood components and fractionated products are also provided to hospitals at no cost. In many other countries (e.g. the U.S., the U.K, and Sweden), hospitals are charged for blood components and fractionated products.

5.3 The Customer Perspective on Performance

A hospital survey was carried out by the consulting team between June 17th and July 10th, 2002 as part of the performance review. The objectives of the survey were to:

a. Give hospitals an opportunity to provide input into the review
b. Understand hospital requirements for blood components
c. Assess hospital satisfaction levels with the provision of blood components
d. Identify opportunities for improvement

The survey looked at the performance of CBS from the customer perspective.

Order Lead Times

Respondents were asked whether order lead times (from order placement to delivery) consistently meet their requirements. Eighty-three percent of hospitals indicated that order lead times did meet their requirements. For the 26 hospitals (12%) that indicated they did not, reasons cited included the following:

- Mix-ups by CBS, bus stations and/or taxi services
- Lateness of new drivers standing in for regular couriers
- Long distance from blood supply
- Transportation problems (not specified)

- Problems with after-hours and statutory holidays (not specified)
- Limited bus service to area
- Limitations imposed by flight departure times
- Order placement requirements (i.e., having to place orders by 11am)
- Unavailability of required product
- Changing needs of acute care
- Staffing levels
- Shipments transported by bus being lost

A total of 209 hospitals responded to this question. A breakdown of responses by province and hospital size is included in Appendix F.

Unusable blood products

Ninety-one percent of respondents indicated that less than one percent of blood products ordered are unusable due to improper processing, packaging or handling. Five percent of hospitals indicated that between one percent and five percent of blood products ordered are unusable. One hospital indicated an unusable percentage over five percent. A total of 213 hospitals responded to this question.

Mechanisms to deal with blood product quality issues

As to whether there is a clear mechanism in place to relay blood product quality issues to local Blood Centres, the majority (86%) of hospitals indicated that there was while only 12% indicated that there was not. A total of 217 hospitals responded to this question.

The majority of respondents indicated that they had no issues regarding how CBS is able to manage product quality related issues with the local blood centres. Results of the question "How would you best describe your local Blood Centre's ability to handle blood product quality issues?" are summarized in the following table.

Exhibit 5-21: Product Quality Responses

Response	Percentage of respondents
Action is swift and product quality follow-up occurs for a defined period	28%
Pro-active communication to ensure no product quality issues exist	23%
Records issue but action is slow	8%
Actions are taken initially but no follow-up	6%
No mechanism in place to handle	4%
Records issue but no noticeable action is taken	3%
Other	14%

Other comments made by the hospitals concerning the Blood Centres' ability to handle blood product quality issues included:

- Not sure if any mechanism in place
- Some respondents do not deal directly with CBS
- Some respondents had not experienced any blood product quality issues or not enough to answer the question

Fourteen percent of respondents did not answer or gave an ambiguous response.

Meetings and other types of support from the local Blood Centre

Forty-eight percent of respondents indicated that they had not had any meetings with representatives of their local Blood Centre over the past year. Forty-three percent reported between one and three meetings. Only one percent reported ten or more meetings. A total of 214 hospitals responded to this question. A detailed analysis of meetings with the local Blood Centre representative in the past year, by province, is provided in Appendix F.

Respondents were asked what type of support is provided by their local Blood Centres. Responses, in order of frequency, were as follows:

Exhibit 5-22: Support Responses

Type of Support	Percentage
Information sessions on new and emerging products and research	32%
Educational sessions on transfusion medicine	27%
Educational sessions on utilization management	18%
Written information (e.g., newsletter, literature etc)	12%
Meetings	10%
No support	8%
Fax communication	8%
Telephone communication	5%
Memos/Notices	5%
Customer updates (e.g., letters)	3%
Symposiums/Seminars	2%
Other	4%

Of those respondents who indicated that they did receive any of the types of support listed in the table above, the majority (62%) found the support to be useful. Nine percent were neutral, and 2% found the overall effectiveness of the support to be poor. Seven percent did not know how they found the support's overall effectiveness.

Forty-one percent of respondents indicated that since September 1998, when CBS was established, neither their local Blood Centre nor CBS has ever contacted their hospital to get input on their level of satisfaction with the level of service they provide. However, a significant percentage (29%) indicated that they did not know. Twenty-six percent reported that either their local Blood Centre or CBS has contacted them in this regard. A total of 211 hospitals supplied this information.

Of the 57 hospitals that indicated they had been contacted, 42% indicated they had been contacted in 2002 while 35% had been contacted in 2001 and 2% had not been contacted since 1999. The remainder of respondents indicating they had been contacted (19%) did not provide the year of last contact. Summary results by province are provided in Appendix F.

Customer Satisfaction Assessment

In order to understand the type and magnitude of change the hospitals have experienced with CBS as their supplier of blood components and fractionated products, a customer satisfaction assessment was incorporated in the survey. The purpose was to gain an understanding of the perceptions and attitudes the hospitals held with regard to three dimensions of customer service, namely, timeliness, product quality, and service.

The respondents were asked to indicate on a scale ranging from "very good" to "very poor" their opinion against specific statements related to the three customer service dimensions being measured. The results are summarized below.

Exhibit 5-23: Summarization of Customer Service

Timeliness	**Percentage of Respondents**					
	Very Good	**Good**	**Neutral**	**Poor**	**Very Poor**	**No Response**
Responds in a timely manner on CBS related enquiries	40	**48**	6	2	1	2
Provides products in a timely manner	**45**	**45**	4	1	1	3
Is time sensitive with minimal delays in processing orders	**47**	43	7	1	0	3
Provides appropriate information and status of orders in a timely manner	**41**	41	11	5	1	3

The majority (64%) of respondents indicated that there had been no change in timeliness since 1998. Twenty-seven percent indicated that there had been an improvement, while only six percent reported that the situation had worsened. A total of 213 hospitals responded to this question.

Exhibit 5-24: Timeliness

Product Quality	Percentage of Respondents					
	Very Good	Good	Neutral	Poor	Very Poor	No Response
Continuously monitors process to ensure integrity of components	41	**45**	5	1	1	7
Identifies opportunities for improvement	26	**45**	19	1	1	9
Is effective in fulfilling current mandate	30	**46**	14	0	0	11

Thirty-five percent of respondents felt that product quality had improved since 1998, while the majority (56%) felt that there had been no change. Only one percent of respondents felt that quality had worsened. Eight percent of respondents did not answer or gave an ambiguous answer.

Exhibit 5-25: Product Quality

Service	Percentage of Respondents					
	Very Good	Good	Neutral	Poor	Very Poor	No Response
Local Blood Centre is a valuable resource	**43**	37	12	2	1	5
Has a structured and effective order management process	38	**45**	12	1	1	4
Is able to consistently deliver "full orders" of blood components on time	33	**47**	12	5	0	4
Is responsive to customer needs and therefore is a good "supplier"	4	**45**	39	10	3	1
Works to ensure customer requirements are consistently met	4	42	**44**	9	2	0

A majority (60%) of respondents indicated that service had not changed since 1998. Thirty-three percent said that services had improved, while only three percent said that services had worsened. Four percent of respondents did not answer or gave an ambiguous answer.

Hospital Suggestions for Improvement and Other Comments

The hospital questionnaire provided two opportunities for respondents to share comments on the performance of CBS. In one question, respondents were asked what changes they would like to see to improve customer service and efficiency in the CBS supply chain. In another question (at the end of the survey), respondents were asked if they had any comments they wished to share. The responses to both of these open-ended questions have been analyzed. Using thematic analysis, responses have been grouped into categories and common themes have been identified. The results are presented below. In many cases, direct quotes from the respondents have been captured in order to emphasize the "voice of the customer" and add richness and credibility to the overall results.

Suggestions for Improvements

For the purposes of analysis, the major suggestions for improvement were divided into categories. The responses are summarized according to these categories in the following table. The actual number of respondents providing each type of suggestion is shown in parenthesis.

Exhibit 5-27: Hospital Suggestions for Improvement

Changes	Percentage of respondents
No change/satisfied	14% (31)
Better/improved transport services (e.g., bus, courier)	13% (28)
Better administrative communication (including notification of shortages)	11% (24)
More educational sessions	7% (16)
Better access to CBS (i.e., distance, location)	5% (10)
Less paperwork	3% (6)
Need more donations	3% (7)
Provide name of contact person	1% (3)
Better verbal communication skills	2% (4)
Computerize the system	3% (6)
No response	45% (100)
Other	6% (14)

Below, is a more detailed discussion of the suggestions made for improvement.

Better/improved transport services

In terms of delivery, a commonly recurring theme was the need to improve transport of products to be more efficient, reliable, and flexible, with one hospital indicating that service is dependent on transport services. A number of hospitals wanted to see an improved courier service. One hospital noted that this would reduce dependence on third party carriers. More specifically, one hospital wanted to see earlier delivery of Loomis orders, noting that they sit in the warehouse overnight. One hospital suggested cost sharing for sending product out by taxi when no other mode of transport is available.

One respondent noted that there needed to be a better tracking system when products travel by bus.

With respect to packaging, one hospital suggested standardizing packaging for shipping across Canada so that every CBS centre is doing the same thing.

Recommendation #90: Hospital survey respondents provided a number of suggestions for improvement of customer service and efficiency. The most common area identified for improvement was transport services. Since this review did not permit a detailed examination of specific hospital concerns, it is recommended that CBS conduct an investigation into hospital satisfaction levels and issues in relation to transport services.

Better administrative communication

One hospital simply wanted *"better communication"*. Communication concerning orders that have been placed was an issue, with one hospital wanting to see more consistency in following through on faxed orders by telephone, and others wanting to receive order confirmation (including status of their order), with one noting that "*we would like a quicker fax back reply to orders that are placed. Order confirmations are often not received by the time the day staff is gone (1600hr). Sometimes we wonder if the order got through [and] sometimes we call to confirm and that's a waste of everyone's time!*"

In terms of asking questions of CBS, one hospital wanted more meetings with their local Blood Centre. Another wanted to see better communication amongst CBS staff so all questions asked receive the same consistent and accurate answers. Another reported that "*When we ask questions I would like an answer – they never get back to me.*"

A suggestion was made that there be better communication about the availability of fractionation products, the respondent noting that they had been unaware for several years that a particular fractionated product was available.

One hospital wanted to see better access to CBS management, noting that *"everyone is always on voice mail at the same time"*.

Two hospitals wanted to see CBS consult with hospitals before changes are made in delivery methods which impact on hospital staff/space requirements. Another respondent wanted to see on-site visits by CBS to the hospital blood bank.

One respondent wanted to see collaboration between CBS and the Blood Conservation Clinic Transfusion Co-ordinator regarding autologous donations.

Notification of shortages / delivery time etc.

At least four hospitals wanted to receive notification of product shortages before their orders were put in and two of these also wanted CBS to have a better understanding of difficulties hospitals face as a result of blood shortages. As one hospital put it, "*patient safety is jeopardized when we are not notified promptly. We should not have to argue, beg and plead for product. Our wastage level is very low. We need it! CBS have little or no understanding of hospital/patient issues – we are unable to predict when emergencies will occur. Some CBS staff on call after-hours make it clear that they are not happy to be called out to issue product. NO sense of patient requirements.*"

One hospital noted that when a product is unavailable from CBS, it would be much easier if they could be notified when it becomes unavailable rather than reordering over and over again. Another hospital said that if there are changes regarding obtaining products that they would like to be notified prior to implementation.

It was suggested by one hospital that CBS notify their acute care department of the expected delivery time and arrival and method. Another wanted better / quicker communication as to when product is arriving if it is being transported by air i.e., information about what flight it is on.

Education/Support

A number of hospitals wanted to see increased and/or more effective education (e.g., workshops, teleconferences, power point presentations) for physician, nurses and/or technologists. One hospital reported needing more access to professional help regarding the appropriate use of blood products and education relating to new products. One respondent said that they get a lot of information memos on products they have never heard of and have no idea who needs this information. Another hospital with a similar complaint recognized the need to inform but found information provided to be irrelevant to a small, rural hospital.

One hospital, a very small acute care facility that orders blood product for specific patients noted that they would appreciate a manual (covering issues such as procedures, how long they have to keep paperwork, how it should be filed, etc) for hospitals of their size. Another two hospitals wanted more information regarding transfusion protocol for blood products while one wanted to see better guidelines for the emergency donor program.

One hospital wanted to see access to help available after-hours.

Distance

A number of hospitals in rural areas (e.g., in Newfoundland, New Brunswick, Alberta, Manitoba) reported that distance is a problem in terms of effective and reliable delivery times. One hospital in Alberta said that their problems all lie in the transportation from CBS to their facility, with only one bus per day from Edmonton and one bus going to Edmonton. One hospital in Manitoba noted that for urgent needs, family members have driven to pick up the required blood.

Some hospitals emphasized that distance means it is difficult to get product on time in emergencies (e.g., in Newfoundland and Nova Scotia). One hospital in Newfoundland said that as such they cannot afford to let supply drop to emergency levels.

Distance was not always reported as being a problem, for example, one hospital in New Brunswick said that "*given the distance that exists between our hospital and CBS, I think we receive excellent service. With our inter-regional network, we have also kept product expiration at an all time low. I am pleased with the service and can not think of any changes that may improve services.*" Similarly, one hospital in northern Manitoba said "*I believe it is as good as it can be considering where we are geographically*".

At least three hospitals in Saskatchewan made reference to the closure of the CBS site in Saskatoon. One hospital noted that the closing would affect their blood supply due to there only being one bus available from Regina. Another expressed concern that while service is good now, the forthcoming changes mean that their nearest centre will be further away with no direct transport service to get blood products to them in a timely manner. They are sceptical about assurances that the service will be maintained as they are now. Another hospital wanted to see the Blood Centre remain in Saskatoon rather than having a central location in Regina which they said is "*central to nothing*".

Less paperwork

Four hospitals made suggestions concerning the required "special access approval" for certain products. One hospital suggested doing away with the requirement as it is too cumbersome and difficult for hospitals to manage. Another wanted CBS to deal with special access in order to decrease the bureaucracy and noted that nothing is done in a timely manner. Another two hospitals simply suggested streamlining the process.

Computerization

A number of hospitals wanted to see a computerized system linking all hospitals with CBS so that product inventories can be identified and moved more efficiently.

In terms of ordering, two hospitals indicated that they wanted to see an electronic means of ordering blood products.

Need more donations

Concerning donors, one hospital suggested that tele-recruitment be done by more knowledgeable people who have some medical background. Two respondents felt that there are not enough donors.

One hospital wanted to see an Autologous Donation Service at the local permanent CBS clinic as well as 24/7 antibody identification.

Provide name of contact person

One hospital suggested an explicit directory of who to contact if problems occur. Another thought it would be helpful for Blood Centres to designate a specific hospital liaison person who is familiar with their operation. One hospital suggested that it would be very helpful to have a permanent Customer Service Co-ordinator to travel to hospitals on a regular basis.

Better communication skills

With respect to the issue of communication, four hospitals noted the importance of having people with good communication skills and a clear understanding and grasp of the English language to answer telephones at their local Blood Centres.

Other

With respect to ordering, one hospital wanted to see a standardized format for blood component requests. One respondent said that they would like to be able to leave an order for products "after hours" rather than phoning the technician "on call". One hospital suggested a system of automatic substitution of products when stock is low.

One hospital said that previously they were able to rotate stock every two weeks to avoid outdating and return units to CRC to be issued to high volume users. They would like to see this system implemented again because of outdating issues that occur in small volume hospital sites. On the same theme, another hospital wanted to see a better mechanism to return older units from remote rural locations so they can be used before they are outdated.

One hospital reported needing a better mechanism to deal with problems and noted that they have had frequent breakages of AFFP (Apheresis Fresh Frozen Plasma) bags with no resolution as yet.

Regarding customer service, one hospital said: "*we would like to see CBS recognize that they are a service organization and that their customers are the hospitals. As such* *they should determine the needs of their customers and respond appropriately rather than rely on the response that "our regulations will not allow us to do that"."*

Concerning management of CBS, one hospital said that "*overall the service is good. I would, however, prefer to see a Blood Transfusion/Hematology specialist in the Medical Director's position. Some clinical decisions are made mainly on cost of product rather than on the need of the patient. I wonder if this might be different if the expertise of the Medical Director was Hem/BB.*"

A suggestion was made that a better mechanism be introduced to deal with platelet requests. One hospital suggested that the turnaround times for NAT needed to be improved so that platelets are available sooner. Another suggestion regarding platelets came from a hospital that wanted to change the days of collection or number of days for collection. This hospital said that a three-day collection break causes problems in supplying platelets that have a five-day expiry date.

It was recognized by one hospital that problems with product supply are not always CBS's fault: "*often with fractionated products it's the supplying company that cannot meet demand therefore limiting our supply e.g., for a 0.5 vial of HBIG we are issuing 5ml. Also, factor VIII is cut back to half orders resulting in more frequent ordering, more work for us and CBS to process orders.*"

One hospital wanted to see a better system organized for small hospitals to send in samples for antibody investigations and antibody investigation turnaround times improved.

A general suggestion was made by one hospital that CBS needed a better understanding of hospital issues.

A suggestion was made by one hospital that CBS consult with users as to the placement of labels on fresh products: "*e.g., computer generated label used by hospital has to be placed over part of the blood label and if computer label has to be removed it tears off some of the original label at the same time*". The same hospital reported that duplicate unit numbers for fresh products increase its workload dramatically and opens the possibility for clerical errors to occur.

With respect to the EDR process, one hospital suggested that there needs to be a complete rework of the EDR process.

Additional Comments

Respondents were given the chance to make any additional comments about the CBS supply chain. A selection of these comments follows:

A concern was raised by one hospital that they have missed getting orders following failure by CBS to confirm if the order has been received and/or processed. The same hospital said that they had requested a change in CBS labelling of A/B series blood because the lab was experiencing difficulties with the receipt of duplicate unit numbers and that on speaking to CBS they were told that it was the hospital's problem and they should contact their software provider.

One hospital reported utilizing the services of another entity for distribution, inventory confirmation and inventory utilization management and stated that the service received from this entity was "*preferable to CBS as it is more personal, timely, hassle free*".

A Toronto hospital reported that the Toronto Centre had been a valuable resource organizing and hosting an SOP/Draft Standards series for Blood Banks to help them with meeting the Draft Standards. The same hospital said that "*Toronto Centre (and probably the whole CBS) should be commended on their handling of Sept 11/01*".

One respondent noted that the CBS website may be useful to the public but it has little value for medical/technical staff. The respondent continued on to say: "*I had hoped this would be useful support service and communication avenue ... having spent a lot of money, I am yet to be convinced of significant return when CBS and CRC are compared*".

One hospital said that technical advice on screening / crossmatch difficulties is very poor and that CBS seems reluctant to give advice in this regard. This hospital said it would like to see bloodbanking policies / procedures standardized across the country because at present they seem to be different for each individual hospital.

Not all respondents blamed CBS for product shortages, indeed, as one hospital noted, "*CBS often cannot fill orders but their product is "produced" only as a result of the generosity of the Canadian population, therefore they are not totally in control of the supply*".

However, as another hospital stated, "*if donations are down, obviously CBS cannot provide all ordered products to all hospitals. However, demands on hospital blood banks is constant (more or less). Sometimes, they (CBS order desk staff) seem to lack appreciation for our situation. We are not located near CBS, so waiting for our order to arrive for replacement of used products can be a nerve-wracking experience.*"

Also on the subject of blood shortages, one respondent noted that "*the blood shortages of specific groups that were common prior to Sept 11/01 were gone for a while but now seem to be back! It is frustrating to have to pay for additional[sic] blood shipments that are necessary when we don't have our routine orders filled due to shortages. Another frustrating situation is that we have had to cancel our Autologous program due to budget cutbacks (the programs are not funded by the medical plan) and the provincial centre is too far away to offer the service. It would be helpful if the nearby* *donor clinics would take this over but we have been told that they will not be doing it due to cost."*

In terms of CBS responsiveness to hospitals' needs, one hospital in Edmonton found that*"overall the Edmonton Centre CBS is responsive to our supply needs but has withdrawn support in other areas i.e., testing consultation (crossmatches) and local donor advisement."*

Issues with customer services were raised, for example, one respondent said *"I believe that the front line workers are doing the best they can with the limited resources they have available and under the current structures that are in place. Unfortunately, when specific needs of the hospital/patients are presented, there does not seem to be any positive type of response from CBS to provide appropriate blood products. Instead it is a "can't do" attitude rather than what can we do for you".*

Another hospital suggested that *"the position of the customer service co-ordinator is necessary for the CBS to continue its improved customer service."* A hospital in Vancouver reported that *"Customer service representative position at Vancouver site was a very good idea."*

With respect to orders, one hospital said that *"we don't want to have one telephone number for the whole country to order products. There would be no negotiating and no personal interest in specific needs."*

A hospital in British Columbia made a point that is likely relevant to a number of hospitals in remote locations, noting that being on an island with no roadlink to the nearest CBS centre requires maintaining high stock levels.

Frustration was expressed with the bureaucratic machine of CBS. One respondent opined that "*since the CBS took over from the Red Cross as blood supplier we have not seen a great deal of change in services. We have the same blood shortages we had before and the same difficulties working with our local centre whose "hands are tied" by Head Office. BC has great transportation problems and isolation problems that were never solved by the Red Cross and are still not addressed adequately by the CBS. I must emphasize that the people who work at the Vancouver Centre do a superb job working within a still unwieldly bureaucracy."*

Frustration was also expressed by a respondent who said that*"our perception of some of the process improvement was to shift the cost to the user not improve the process (e.g., set delivery times of products creates no room for flexibility and pushes delivery costs onto the hospital). Even if the run hasn't left yet they won't add a stat request."*

In summary, the results of the hospital survey suggest that hospital customers are reasonably satisfied. There is fairly high satisfaction with product quality and timeliness of deliveries. Hospitals appreciate the educational sessions offered by the

Centres. Key areas for improvement are in transport services and overall customer service. Also, further investigation of cancellation of elective surgeries should be conducted to find ways to eliminate such occurrences.

Recommendation #91: The hospital survey found that a high proportion of hospitals have never been consulted by CBS (local or national) about the level of customer service they receive. It is recommended that CBS develop and implement a National Customer Service Strategy. The strategy should include ongoing mechanisms to measure hospital satisfaction levels with the various services that CBS provides. The strategy should also identify the core basket of services that CBS offers hospitals at both the local level and national level, for example free routine deliveries of required blood components and fractionated products, educational sessions, regular meetings, bulletins, newsletters and information lines. Consideration should be given to administering a regular hospital survey similar to the one conducted for this review.

6. Assessment of Risk Management Mechanisms

6.1 Introduction

6.1.1 Integrated Risk Management

A comprehensive enterprise-wide approach to risk management is increasingly recognized as a necessary requirement for the modern complex organization. This approach incorporates a structured and methodical self-assessment process, where organizations seek to achieve their objectives through the alignment of objectives, risk, response and actions.

Risk can be defined in many ways. In the broadest sense, risk is ‘anything (internal or external) that affects the achievement of objectives of the organization’. Risk is normally inherent in the activities of any organization, but it is almost always the product of choices. In the context of CBS, the definition of risk can be focused somewhat to mean ‘the possibility of adverse consequences.

The dimensions of risk include:

1. ***Hazard:*** ensuring that bad things do not happen, by preventing exposure to risk from turning into actual harm;
2. ***Uncertainty:*** coping with uncertainty, change or the unknown, by monitoring variances from expectations internally, and gaining knowledge from the external environment;
3. ***Opportunity:*** making sure that good things do happen, by proactively harnessing risk through risk foresight, planning and management, freeing up the organization to achieve its positive objectives

Effective risk management requires a systematic consideration of the full range of methods to respond to risk. It involves:

1. Continually and systematically identifying risk issues, understanding how risks impact other risk factors, gathering knowledge of those issues and their implications for the organization as a whole;
2. Analysing and prioritizing based on both the knowledge and the gaps that remain;
3. Developing and selecting the best options for the circumstances;
4. Executing the chosen options, including communication of plans and expectations; and
5. Monitoring the situation, continually repeating the process as circumstances change.

Risk response strategies include avoidance, mitigation and control, transfer and/or acceptance of risk. Finally, it is critical that objectives, risk and response be aligned for successful performance up, down and across the organization. Integrated Risk Management means providing a systematic and disciplined method for managing risk that is applied to all aspects of risk within all parts of the organization. This will be the foundation for the results presented in this chapter.

6.2 Current Risk Management Process at CBS

6.2.1 The Context for Risk Management Development at CBS

Since its inception in 1998, CBS has undoubtedly been a risk-conscious organization. The context of its creation was heavily laden with concern for the potential and actual harm caused by an unsafe blood supply. No one involved in this field in the last two decades, whether with the previous operator, the Canadian Red Cross, or with the CBS, is ignorant of the critical importance of safety. The Krever inquiry and the events and publicity that followed it are prominent in the memory of all concerned.

Risk-consciousness and risk-awareness are not necessarily the same concept. As noted in the Krever report, the previous operator was conscious of risk, but there were problems involving the identification and analysis of risk. For example, it was found to have waited for proof of a clear medical connection between evidence and harm before planning and acting, rather than taking prudent steps based on the probability that such a connection existed[51]. This indicates the lack of a clear, well-thought out and continuous process for identifying and analysing risk in the context of the organization's overall objectives and purpose.

The fact that an organization has always been conscious of risk does not mean that it has always been engaged in risk management as a discipline. But the practice of risk management involves a systematic and structured approach to risk, using established, documented and standardized approaches and methods specifically designed to suit the organization.

In that context, it is fair to say that the discipline of Integrated Risk Management did not exist in CBS when the organization was created. While most of the governing corporate documentation leading to and following creation of CBS either directly or implicitly mandated promoting the discipline of risk management, the development and implementation of an integrated program takes significant time. This assessment must recognize this. Bearing in mind the complexity of this organization, the climate in which it was created, the changes that it has already undergone, as well as the extent of change required to implement integrated risk management, it is not a surprise that this is still in implementation stages at CBS.

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[51] See Commission of Inquiry on the Blood System in Canada, Final Report, Part III, p. 294: "Assessment of Risk"

6.2.2 Current Risk Management Architecture

The structure within which risk management takes place is in a number of documents. The list below can be seen as progressing down through the organization, moving from the general to the specific, and providing more detail and rigidity as it progresses. This closely parallels the management control structure of the organization. Figuratively, the shape resembles a multi-level pyramid (See diagram below).

The first layer consists of the documents that initiated CBS:

Founding Agreement: Federal/Provincial/Territorial Memorandum of Understanding (MOU)
Founding Documents: Letters Patent, Initial Bylaws

Below this layer are documents setting out policies and providing guidance:

Board Policies: Mission, Vision, Values, Code of Ethics, Quality Policy, Risk Assessment Policy.

Board Approved Guidance Documents: Risk Management Framework

From the Operational perspective, beneath this layer are a large number of documents that provide increasingly specific instructions. These constitute the methods and procedures that ensure risk management is implemented throughout the organization. In the regulated environment, risk is primarily managed by standardization of processes and practices, ensuring that all activity follows tried, tested and approved methods designed to minimize or contain risk. Heavy reliance is placed on documentation of compliance, and reporting deviations from the norm.

Risk-related decision-making is relatively limited under this framework, focusing on exceptions. However, risk awareness still plays a significant role in the process. CBS staff must be conscious of when the processes create or increase risk, and must use internal mechanisms to identify and resolve these situations (the Change Control Operations Procedure discussed below).

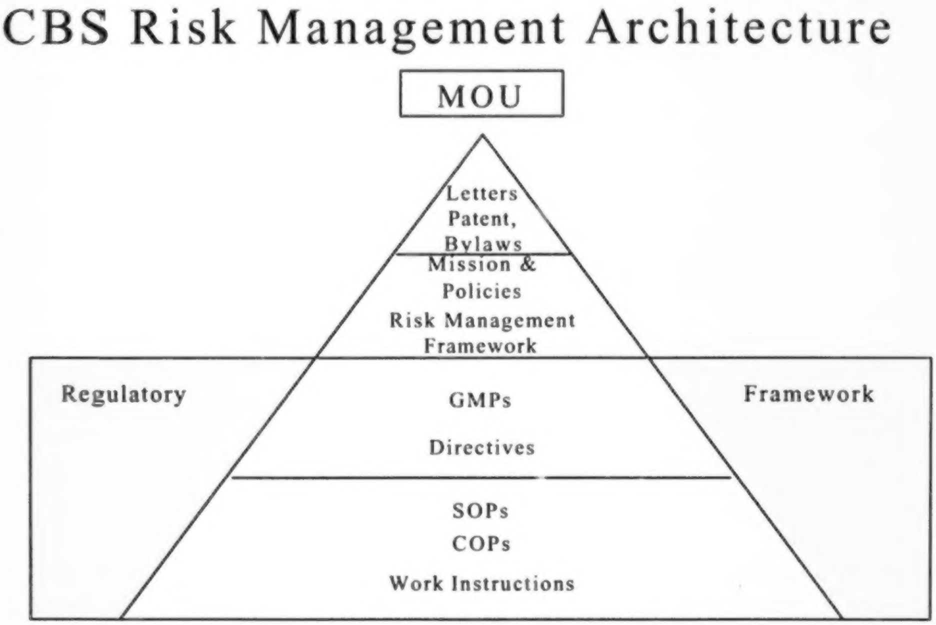
The types of documents found at this level include:

- Good Manufacturing Practices (GMPs)
- Directives
- Standard Operating Procedures (SOPs)
- Centre Operating Procedures (COPs)
- Work Instructions

CBS operations take place within a regulatory framework that dictates much of what occurs at the bottom of this pyramid. Blood and blood products are regulated as

Biological Drugs under the *Food and Drug Act (F&DA)*. GMPs are contained in guidelines within regulations passed under that *Act*. An Annex to those regulations includes blood products. SOPs are the mechanism under which GMPs are implemented. Under the current arrangement, the regulator must approve changes to these SOPs before they are considered to be in compliance with the regulations.

Exhibit 6-1: CBS Risk Management Architecture


CBS Risk Management Architecture
MOU
Letters Patent, Bylaws
Mission & Policies
Risk Management Framework
Regulatory
GMPs
Directives
Framework
SOPs
COPs
Work Instructions

6.2.3 Current Risk Management Mechanisms

Risk Management mechanisms are systems within CBS that control risk, provide monitoring, feed information back to management, and allow for change within the risk management architecture. They include:

- Member reviews
- Board oversight
    - Governance and accountability definition
- Management oversight:
    - Safety and Performance Management independence and oversight
    - Quality Assurance processes
    - CBS internal audit
    - CBS Legal

    - Incident investigation and reporting process
- Regulatory oversight
    - Health Canada external audit
- Insurance
- Emergency Response – see section 5.2.2 on Adequacy and Security of the Blood System
- Competency profiles of employees
    - External accreditation
- Courses and training
- Change Control Operating Procedure

Each mechanism is described briefly below:

Member reviews

The MOU provides for regular member oversight regarding CBS, within the governance structure established. Direct external management audits, and targeted audits may be conducted at their discretion. This review is an example of that process in action.

Board Oversight

Risk management is the responsibility of the Board of Directors. The Board of Directors may assign oversight of risk management to a committee of the board; nonetheless, the responsibility for risk management remains with the board and all its members.

The Board of Directors must charge management to propose, for its consideration and approval, a risk management infrastructure including operating policies and tolerances. The risk management infrastructure must balance, to the satisfaction of the Board of Directors, the competing need for resources with the probability of event risk.

The Board of Directors should have resources and information at its disposal to satisfy itself that management's recommendations are appropriate and in keeping with industry "best practices". Resources at the disposal of the Board of Directors would include control over the mandate of internal and external audit services and a budget to retain external consultants. These resources, in conjunction with effective and timely management reports, would give the Board of Directors the wherewithal to ascertain the adequacy of the risk management infrastructure.

In fulfilling its stewardship role, the Board of Directors must work with the CEO and senior management to ensure the right risk management governance is implemented. Nonetheless, the Board of Directors must impose, through its activities (e.g., control of audit agendas), an additional layer of due diligence to monitor, test and assess the risk management infrastructure – and if necessary take remedial action.

In supervising management, the Board of Directors must have both the ability and resources to act independently and set the agenda of internal and external auditors.

Management Oversight and Quality Assurance

There are a number of mechanisms for management oversight. CBS Legal has been given responsibility to develop the risk management framework, as it is essentially a policy-level document. However the legal department plays more of an advisory or responsive role when it comes to day-to-day risk management.

Prime responsibility for risk management at the policy and governance levels resides with the General Counsel. Responsibility at the operational and tactical levels resides in the Safety & Performance Management (S&PM) department at CBS. S&PM is responsible for implementing risk management across the operations at CBS.

Recommendation #92: There is some concern with the manner in which the function of the Chief Risk Officer is currently divided between the General Counsel and the Executive Vice-President Safety and Performance Management. As a general practice, a single point of management is the clearest approach to ensure delivery. An additional level of due diligence is introduced in many organizations through a cross-functional risk oversight committee of peers (usually comprised of CEO direct reports). The risk oversight committee is charged with reviewing and signing-off on all risk management related matters before they are tabled with the CEO. Thereby, bringing to bear a multi-discipline, cross-functional, corporate forum for vetting of all proposals in relation to their risk profile. It is recommended that CBS make the establishment of this type of risk management committee an organizational priority to that it is introduced in a timely manner.

The reporting structure has been changed to ensure independence between the quality function and the operations function. While Quality Assurance staff formerly reported at the Centre level, they now report through to the Executive Vice President of S&PM. Quality Assurance staff have been given the power to stop operations in progress, and it is planned for them to have ultimate sign-off authority on CBS products in future. Quality Assurance also signs off authority in hiring, to approve any proof of qualifications submitted by new employees.

There is a quality program within operations. Under the guidance of S&PM, the organization has obtained first-level accreditation under the National Quality Institute's Canadian Framework for Business Excellence for process improvement. This means that plans are in place to implement a continuous improvement model within CBS.

Each Centre has Quality Systems Associates and a Quality Systems Manager. Their role within the Centre includes: approval of Centre Operating Procedures along with the Centre Director, regular departmental audits, review of incident reports, review of Health Canada audit results, monitoring of action plans to address audit observations and training.

Supplier validation takes place. Quality Assurance follows a standard process for supplier validation, which includes supplier site visits for validation audits.

Internal process audits are conducted regularly to ensure compliance with regulations, as well as internal rules and policies. Regular reports are prepared on these results, including trend analysis. Some analysis is conducted to seek the root causes of compliance deviations.

In addition to process audits, internal audits are conducted regarding business risks. These focus on areas not covered by S&PM auditors, and are outsourced. The contractor has submitted a draft audit plan[52] that includes both a business risk framework, and an analysis of CBS business risk exposure broken down by category.

CBS has standard processes for investigating incidents that may impact the safety of the blood supply. Specific processes and actions vary considerably depending on the nature of the problem identified. Rules are provided regarding reporting levels, look-back and trace-back procedures, notifications, product recalls, and other activities related to risk mitigation and response.

Regulatory Oversight

CBS facilities (including Head Office) are audited by Health Canada annually. These audits focus on compliance with regulatory rules and licence requirements. Particular attention is paid to compliance with or deviation from Standard Operating Procedures (SOPs) that have been approved by Health Canada. This is a particularly powerful control, since the potential consequences of non-compliance could involve shutting down facilities, or laying regulatory charges.

Regular reports are provided to CBS on these results. CBS analyzes these data to determine trends, and to determine root causes of problems identified. These reports are provided to management regularly, and are closely monitored to ensure responses ensue. The results of the Health Canada audits are also posted on the CBS website.

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[52] Internal Audit Services Risk-Based Audit Plan – Phase II – Consolidated Results, Analysis of Business Risks and Internal Audit Plan – Oct. 3, 2001

Insurance

Insurance is a standard tool for risk sharing and financing. CBS has comprehensive coverage for typical business losses, and has recently reviewed their coverage in these areas.

But CBS must also insure against catastrophic risk. Commercial insurers would not provide appropriate coverage when CBS was created, so insurance had to be provided through the mechanism of a captive insurance company. A description of CBS' insurance model is provided below:

Primarily due to the catastrophic events of the late '80s and early '90's, it is difficult or impossible to find commercial insurance for blood products and services. The previous operator, the Canadian Red Cross, encountered serious problems with liability insurance. In January of 1986 their liability insurance expired, and was not renewed. This left them exposed to significant liability, as well as causing contractual problems (see the Krever report, p. 528). Commercial insurers are either unwilling to provide policies, or will charge premiums that are prohibitively high.

This problem has certainly not disappeared. Accordingly, CBS has relied upon a program of self-insurance to distribute this type of risk. A captive insurance company has been set up. This is essentially a self-insurance scheme. CBS wholly owns an insurance company, CBSI. This company is set up for the sole purpose of providing insurance against catastrophic loss for CBS. Accordingly, CBS pays premiums to the company, and the company provides insurance services.

CBSI distributes risk mainly through a collection of reinsurance contracts. Under these contracts, commercial insurance companies contract with CBSI to protect against specific or limited parts of the potential liability. In this way, the reinsurers are protected from direct liability to individuals who might suffer loss.

This is a common structure in the insurance industry. In an era where court awards seem to be spiraling out of control, the reinsurers are one important step removed from unlimited exposure to liability. They merely contract with CBSI to deal with specific and limited areas of liability, limiting their exposure accordingly. In turn, this also allows CBSI to limit the premiums paid to commercial insurers, which helps keep overall costs in check.

Of course, as a direct insurer, CBSI remains open to liability claims. Accordingly, CBSI must also maintain sufficient reserves and contingency funds to deal with the remaining liability. This can be substantial. Though not within the scope of this review, it was noted from the minutes of recent meetings that the sufficiency of these reserves is an ongoing area of vigilance for the CBS Board.

The legal separation of CBS and CBSI serves other purposes. It helps ensure separation of roles, providing some level of independence, expertise, and objectivity to the insurer. And separation does provide some measure of credibility in the industry, and perhaps even for the public.

CBSI is incorporated in Bermuda to allow cost advantages. It has its own Board of Directors, though as representatives of the sole owner, two members of the CBS Board share roles on the CBSI Board.

Reports are that the premiums CBS pays to its captive insurer are substantial, prompting a desire to explore other options. However, other options appear limited. Direct commercial insurance could be sought, however the tragedy of September 11th also had an enormous impact on insurers, suggesting that coverage for catastrophic loss will be even less likely now than before.

Options could include legislative reform. One option would be to legislate a limitation of liability for blood products. Political risks make this an unlikely solution. The public's memory of the blood supply tragedy has not waned, and they would likely be unwilling to accept a solution that transfers the burden of loss onto the recipient.

A second possibility would be to have governments collectively provide insurance through a guarantee or indemnity agreement with CBS. This is somewhat akin to the recommendation in the Krever report (p. 1045): "The provinces and territories of Canada should devise statutory no-fault schemes that compensate all blood-injured persons promptly and adequately, so they do not suffer impoverishment or illness without treatment. I therefore recommend that, without delay, the provinces and territories devise statutory no-fault schemes for compensating persons who suffer serious adverse consequences as a result of the administration of blood components or blood products."

While some might suggest that government already serves as the insurer of final resort when it comes to the blood supply, this form of solution also carries some risk. It can be expected to be difficult to reach an agreement across the governments involved. Additionally, formalizing this type of arrangement could lead to higher costs, since it would add to the administrative burden on government, and increase direct government exposure to liability. In the current system, there is a good degree of private-sector and quasi-governmental involvement, which may allow for greater efficiency overall.

It is also possible that CBS could join a group self-insurance scheme. Cooperative agencies exist for the purposes of sharing healthcare insurance costs. One example is HIROC - the Healthcare Insurance Reciprocal of Canada. It is a self-owned insurance plan for not-for-profit healthcare organizations. However in Canada these organizations tend to be geared toward smaller members such as hospitals or nursing homes. While inquiries could be made, CBS may present too much of a risk for these groups, since CBS carries a different type of risk (more product than service) and outweighs the members of the group in terms of exposure by a considerable margin.

The potential for forming or joining an international cooperative healthcare insurance scheme could perhaps also be explored. However while this would allow for greater scale, cross-border differences in legal systems, liability mechanisms and compensation amounts would likely make such a plan difficult to administer fairly and efficiently.

Job Descriptions and Competency Profiles of employees

For appropriate positions, job descriptions should include terms that specifically reference risk management. This issue has been identified at CBS, and should be dealt with during implementation.

The requirement that most employees hold particular qualifications also acts as a risk control mechanism. These qualifications may include the holding and retention of accreditations from outside bodies or professional associations.

Courses and Training

Learning activities also reduce risk. CBS provides training to its employees in a number of ways, such as technical training or courses. Specific training for risk management is scheduled for Phase III of the implementation. Training is a common activity at CBS, in light of the need for ongoing training for regulatory compliance. In excess of 800 positions have training and education requirements, and most involve training for work in a regulated environment.

The organization also has experience and success with training for specific projects. A major initiative for Occupational Health and Safety training has been successfully completed, leading to a turnaround in O&HS compliance. CBS plans to draw on and adapt these plans for risk management training.

Change Control Operating Procedure

CBS has a feedback mechanism for changes to the SOPs. Change requests can be initiated by any staff member, and a set procedure exists to manage and approve these. This process is governed by the Change Control Operating Procedure. This standard process has recently been revised and is in the process of being implemented across the organization. It is comprehensive and detailed.

As part of the internal approval process, any change request undergoes several steps related to risk management. Under the Change Control Operating Procedure currently being implemented, an Impact Assessment Tool is completed. This tool provides a list of questions designed to identify issues and impacts related to the change.

Following the sequence provided in the Operating Procedure, a Model for Risk/Benefit Assessment, also called the Risk Assessment Tool, may be completed. Use of this tool is optional. It provides an approach for analysing risk. It includes a grid for determining risk tolerance, and a checklist for 'Risk Selection', and includes a number of questions to assist in the analysis.

This tool resembles the CBS Risk Management Framework in concept, however it is quite different in form, having been drawn from an external source (noted on the tool itself). To illustrate one difference, a grid is provided upon which 'severity and frequency of loss' can be plotted. This is conceptually similar to the grid provided in Step 2 the CBS Framework, however the format and terminology differ. The framework refers to '*magnitude* and frequency of *harm*' (emphasis added), and additional boxes are provided that provide for 'medium' ratings, and (more importantly) allow the user to classify the factors as 'unknown'.

In the sequence provided in the instructions, a Hazard Analysis Tool is next used to evaluate individual events that might ensue from the change. The event is first identified (presumably using the Impact Assessment Tool mentioned above). Designated staff must be convened from Medical, Legal, S&PM and Operations. A Safety/Efficacy rating is first determined by considering and assigning a number for safety of staff, donors and recipients, or for efficacy of the product. Then a rating and number are determined based on the likelihood of detection of the event at a subsequent critical control point. The Hazard Score is then assigned based on the sum of the two numbers.

Finally, prioritization takes place, based in part on the Hazard Score, as well as criteria set out in the Change Request Priorities table. Should there be an emergency situation, the procedure allows for a speedy approval process, including verbal approval, with retroactive follow-up through the normal change control process. To support these approvals, CBS has an 'Executive on Call' program that ensures that a member of the executive team is available (via pager) at all times.

Ultimately, after proceeding through the internal CBS process, SOP changes must be approved by Health Canada. Significant delay is added since this process is not internal. But the fact that it is external appears unavoidable under the current regulatory structure.

6.2.4 Risk Management Staffing

As part of risk management implementation at CBS, staff is being dedicated to that function. Accountability within CBS is shared. Risk management is a responsibility of the legal department. Legal is responsible for the 'people' side of risk management, at the policy and management level. Responsibility for the 'process' side of risk management falls to the Executive Vice President, S&PM, since the regulatory and compliance aspects of risk are so prominent within CBS.

There are plans to form a Risk Management Committee. Its mandate is still under development. Generally, it is expected to assist in balancing the shared responsibility for risk management, and will help ensure communication occurs across the organization.

A Director of Risk Management has recently been appointed. That position reports to the General Counsel. The Director is supported by the Risk Management Officer. Both of these positions are dedicated full-time to risk management across all aspects of CBS.

6.3 Risk Management Analysis

6.3.1 Risk Management Framework Assessment Criteria

A useful benchmark for a quasi-governmental organization such as CBS is the *Integrated Risk Management Framework* (IRMF) developed by the Treasury Board of Canada Secretariat (TBS).[53] It was developed from a public perspective, focusing on serving all Canadians, similar to the high-level mandate of CBS. It is practical and integrated in its approach, taking an organizational rather than functional viewpoint. And it was recently developed based on 'best of class' research in public risk management.

The status of integrated risk management at CBS was assessed in comparison to key attributes found in integrated risk management frameworks, using the TBS framework in conjunction with internal IBM Business Consulting Services and other Risk Management resources. Input from the Risk Control Division of the Ontario Financing Authority and the B.C. Health Care Risk Management Society was also considered. Evidence was gathered through interviews and review of documentation. Additionally, certain major CBS decisions were traced to determine how they proceeded through the risk management process.

Having recognized at the outset that CBS continues to transform itself, it was appropriate to assess the state of risk management at CBS by following a model that reflects typical stages of progression of an Integrated Risk Management implementation. There are four related elements for Integrated Risk Management that flow from the establishment of a function and strategy, through implementation, follow-through and continuous improvement:

1. **Developing a Risk Profile**

   This includes Assessing Internal and External Environment, Assessing Cultural Risks and Risk Tolerance

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[53] TBS of Canada, April 2001; http://www.tbs-sct.gc.ca/pubs_pol/dcgpubs/riskmanagement/rmf-cgr01-1_e.html

2. **Establishing an integrated risk management function**
   This includes strategic risk management direction, integrating RM into decision-making and building organizational capacity
3. **Practicing integrated risk management**
   This includes common process, decision-making and communications and consultations
4. **Ensuring continuous risk management learning**
   This includes creating a work environment that adopts RM, building RM into learning plans and supporting continuous learning

6.3.2 Developing a Risk Profile

Assessing Internal and External Environment

CBS engages in environmental scanning regarding significant risk issues, both internally and externally. Broader global issues are considered when addressing risk issues. This was clear when specific decisions were traced through the risk management framework. This was also evidenced by an executive presentation to the Board given largely for strategic educational purposes, reviewing all of the types of risks that the organization faces.

CBS staff and management report that the organization is ‘tied in’ to international developments regarding epidemiology and transfusion medicine through contacts in Canada and abroad, and that the state of this communication network is stronger than in the past. CBS recognizes that this is an area where further improvement could be made, and are actively working toward this.

Reports and presentations were reviewed regarding similar international organizations, including reports benchmarking CBS against similar organizations. Management reports outline and summarize internal performance, often providing both data and analysis of implications regarding risk. It was noted that some internal reports place a heavy emphasis on data, and stress deficiencies suggestive of risk, but can be lacking in the analysis to allow conclusions to be drawn that enable action.[54]

Current Risk Management Capacity

Rapid changes are being made in this area. While the organization has had informal risk management capacity for some time (as described above), the capacity for formal, structured risk management is still being put in place.

As the first of four phases of implementing risk management, a plan for roll-out has been developed. Recent changes include the development of the framework, dedicating staff to risk management, separating Quality Assurance from manufacturing, and planning for risk management training of key staff. The second phase, Development, is in progress. A number of initiatives are under development, including the completion of a Risk Management Manual.

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[54] This was the subject of management comment. One example is the Information Systems Problem Management Report.

It is noted that implementation is behind the schedule set in the Risk Management Program Update in February of 2002. This is an area of concern. The specific reason for the delay is attributed to difficulties in staffing and resourcing for risk management. Although the delay may simply be attributed to ambitious planning that did not factor delays into the timelines, it may also suggest that risk management is having difficulty competing for resources within the organization.

There is a significant background issue that compounds the expectation of implementation delay. CBS has had difficulties with past implementations. This is no surprise, considering the magnitude and frequency of change that the organization has undergone. But it does signal that the organization is change weary. A number of sources reported that the culture of the organization has undergone significant change for the better, but that it is still somewhat resistant to change, in large part because of the volume of change that has taken place.

The implementation of risk management is taking place in the context of a large Transformation Project. A number of initiatives will occur in concert. While change is necessary, this increases the change pressure. It will make implementation of risk management more difficult, since it will have to share organizational 'air time' with many other changes.

Risk Tolerance

Awareness of the current risk tolerances of various stakeholders is an important part of developing the risk profile of the organization. CBS's Risk Management Framework does provide an inventory of stakeholders. Indications are that communications with stakeholder groups have improved significantly in recent years. Recent events, including support from groups that formerly appeared adversarial[55], tend to confirm this.

As the CBS framework itself acknowledges, this remains an area for improvement. The general perception within CBS is that the public tolerance for risk in the blood supply is zero. A recent public survey commissioned by CBS reported that 78% of Canadians "share the view that when it comes to operating Canada's blood system there should be zero risks taken and safety should always come first."[56] Some level of risk is unavoidable. In general terms, if the public were fully informed, they would likely accept unavoidable risk. It is preventable harm that is intolerable. CBS must continue to improve the communication channels with all stakeholders, and ensure that those communications are two-way, so that CBS gains a better understanding of stakeholder tolerance for risk.

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[55] In a recent court action, certain special interest groups supported the CBS position rather than that of a gay activist who purposely donated blood in spite of a deferral.

[56] "Winter 2002 General Public Research Program, Final Report, April 2002, Ipsos-Reid Corporation, page 25.

6.3.3 Establishing an integrated risk management function

Strategic Risk Management Direction

The risk management vision, objectives and operating principles of the organization should facilitate integration of risk management into the organization. They should complement the organizations existing vision and goals. Management must be committed to risk management, and must communicate clearly to ensure it becomes part of everyone's job. This direction also includes ensuring risk management implementation is properly communicated and resourced.

CBS has made a good deal of progress in this area. Management is committed to risk management. The communication process has begun. Risk management is still in the process of being integrated into the organization, and it is too early to determine how successful this project will be.

As described above, there are structures and mechanisms to support risk management throughout the organization. These are appropriate, but, as with most organizations, management must strive to integrate a clear risk management approach across all functions.

There is an issue that may be acting as an impediment to strategic risk management direction at the governance and policy levels. To explore this, the governance and policy structure of CBS will be reviewed in greater detail:

The Memorandum of Understanding

The Memorandum of Understanding (MOU) outlines the driving principles behind the Canadian blood supply, including creation of CBS. These principles set the context for the risk management approach.

The ministerial principles include the principle that that 'safety of all blood, components and plasma fractions should be paramount'. A further ministerial principle provides that "a cost-effective and cost-efficient blood supply program for Canadians should be encouraged".

Clause 5 of the MOU acknowledges Federal responsibilities, including the jurisdiction to regulate blood under the *Food and Drugs Act*. Clause 6 deals with Provincial and Territorial responsibilities, including jurisdiction over public health matters that includes the monitoring and reporting of blood-borne diseases. Provinces agree to cooperate with Health Canada and CBS in surveillance for blood borne pathogens.

Risk management is specifically dealt with in several places in the MOU. The MOU specifically mandates "surveillance and monitoring" and "health risk management" as key functions of CBS (Annex A). The Responsibilities set out in Annex A specifically include "establishment of an appropriate risk management regime". Annex B of the MOU sets out the governance model for CBS. This dictates that CBS have "complete management discretion over all operational blood system decisions".

Later, the CEO's responsibilities are described to include ensuring "that all executive decisions are made within an analytical framework of health risk management". The CEO is also given decision making authority and spending powers for emergency safety response.

Management discretion also includes "matters of health and safety with respect to the blood supply system". This is immediately followed by the sentence: "Decisions in this regard will be made within a health risk management framework which places on an equal footing the three critical elements of cost, benefit and risk".

This creates a governance problem regarding risk management. The differences in the wording of these sections provide some uncertainty regarding risk management at its highest level. CBS management have a difficult challenge regarding the issue of risk tolerance. Since risk is always present, the question is: what level of risk is 'acceptable'? What tradeoffs, if any, should exist between risk and any other elements, such as cost?

In the best of situations, there is no clear answer to this question, and discussions regarding it quickly enter the realm of philosophy. For this reason, specific limits cannot be defined in advance, and general policy direction must be provided from the highest levels. The founding document under which CBS is created should provide a clear and consistent perspective from which to approach these issues.

However, while both the key principles and the ministerial principles state that safety is 'paramount', the mandate for the health risk management framework places risk on an equal footing with cost and benefit. Since 'safety' can be defined as "freedom from risk, danger or injury' this poses an understandable dilemma. The key principles behind the MOU dictate that safety of the blood supply should take precedence over other issues, while cost effectiveness should merely be "encouraged" But the foundation for the risk management framework mandated in the Annex appears to elevate cost to equal status with risk.

This apparent inconsistency between the policy approach to safety and the policy approach to health risk management is a cause for concern. It leaves CBS in an uncertain position when decisions are made regarding risk and safety. Though these decisions are never simple, and no policy approach could make them so, a clear starting point would be beneficial. It is one thing to treat safety as the highest priority, and to thereafter weigh the costs of providing better safety against any or all other issues. It is another thing to treat safety as something that is equal to cost and benefit from the outset of the analysis. The MOU as a whole is not clear which approach is to be taken.

CBS Letters Patent and Corporate Bylaws

The founding documents of the corporation cannot be expected to resolve this problem, since they take their authority from the MOU. Risk management is addressed in the Letters Patent of the corporation. The objects of the corporation include:

"D. to develop and implement an appropriate risk management strategy for Canada in relation to blood and blood products."

The objects also provide for risk management activity, such as threat surveillance, monitoring and response, research, and compliance with safety standards, policies and guidelines. But no additional guidance on the relative priority of safety is provided in these founding documents.

CBS Policies

The next level down the governance pyramid is Board policies. The CBS Board has approved a number of policy documents that provide general guidance. These were reviewed from the perspective of risk management. As a group (excluding the policy on risk management) they strongly suggest that safety takes precedence over financial issues. However, they do not resolve the issue as clearly as might be hoped. It has been noted that the lack of clarity in the MOU makes a direct resolution difficult.

CBS' Mission Statement refers to " gaining the trust, commitment and confidence of all Canadians by providing a safe, secure, cost-effective, affordable and accessible supply of quality blood..." While at first glance safety may appear to be given equal treatment with cost-effectiveness and affordability, the entire context is defined in terms of gaining trust. This arguably places safety on a higher plane, since safety is naturally more crucial to trust than cost issues.

The Vision Statement echoes these words, and adds: "Emerging risks and best practices are monitored continuously. Our blood and blood products are safe and of quality". The Value Statements of the organization also highlight safety and quality by referring to these in the opening statement. Cost is indirectly referenced in the context of "stewardship of public funds" and "value-driven".

There is a Quality Policy. It recognizes that Canadians rely on CBS for blood products that are "safe, effective and consistent." There is a Code of Ethical Conduct. It provides four equally important principles to guide decisions and actions, two of which are "non-maleficence - …minimize harm and maximize benefits", and beneficence - …strive to do good". Cost implications are indirect here also.

There is a Risk Assessment Policy. Its purpose is to outline CBS' responsibility in ensuring the safety of the blood system, again placing safety first in terms of priorities. It provides for compliance with regulations and the conduct of risk assessments. A 'basket' clause provides that all decisions should be based on a reasonable standard of care using professional judgement based on scientific review. Again, cost does not figure directly in the policy.

The promotion of safety above other considerations in these policies is understandable. Paramountcy of safety was perhaps the single clearest message coming out of the Krever Report, and is a common theme across most international blood agencies. These policies all agree with the key principles regarding safety set out in the MOU.

Recommendation #93: It is recommended that Board policies be reviewed to ensure congruence with risk management. Several policies can be seen as touching upon risk. Once clarity is provided regarding the relative status of risk, these policies should be rationalized accordingly. In particular, the Risk Assessment Policy could be broadened into a Risk Management Policy. If the wording could be modified to ensure that the 'reasonable standard of care' described encompasses good risk management practices. And the apparent bar could be raised to make it the goal to exceed the regulations, rather than to comply with them.

CBS Risk Management Framework

As mandated by the MOU, the Board of CBS has approved a framework to guide risk management at CBS.[57] It sets out the objects of the corporation as set out in the Letters Patent. It also provides references to materials and literature used to develop the framework.

This framework is structured, comprehensive and focused on the needs of the particular organization. It follows a logical sequence. Although the TBS *Integrated Risk Management Framework* against which it was compared was not specifically referenced (likely due to concurrent timing of development), ready comparisons can be made between the two. By and large, the comparison is favourable for CBS. (A full analysis of the two appears below.)

It must be noted that the Risk Management Framework does not specifically resolve the governance issue concerning the importance of safety. In light of the conflict in the MOU, it does not (nor, we believe, can it) clarify whether safety is the primary consideration, or whether it is of shared importance with other factors.

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[57] It is understood that this policy is currently under revision.

Step 3 in the Framework is designed to deal with the "Identification, Analysis and Prioritization of Risk". This section discusses how "one has to come to terms with the accepted level of risk one can tolerate given the benefits…". In accordance with best practices, it is noted that partners and stakeholders must be consulted in this stage of the analysis. However, it is not noted whether safety should be considered paramount at this point in the analysis. Presumably this difference could affect whether the analysis continues to the next stage.

It is possible that this was overlooked because the framework is designed for any type of risk, including risks that have little direct effect on safety. But directly or indirectly, safety is critical to all activities within CBS.

Step 4 deals with the "Identification and Analysis of Options". These options may allow the risk to be coped with, by lowering risks or dealing with consequences. This is the natural point where costs enter the picture, since 'up front' expenditures to deal with risk are common, rather than 'after the fact' expenses incurred as a response to consequences. Accordingly, the Framework references the MOU. As might be expected, the specific MOU requirements dealing with risk management are cited, placing risk on an equal level with cost and benefit.

This is not in and of itself a criticism of the Framework. The Framework accurately reflects the priorities specifically set out for it in the MOU. The problem is that in doing so, the principles in the Risk Management Framework are not aligned with the key guiding principles in the MOU, and therefore are not aligned with the principles set out in other policies of CBS. This misalignment is founded in the wording of the MOU.

Recommendation #94: Should agreement on clarification of the MOU (see recommendation #1) prove to be practically impossible, it is recommended that the CBS Board directly deal with the conflict. The Risk Management Framework should be amended to specifically note the apparent differences in the principles stated in the MOU. The Framework should address these differences, and resolve them if possible. This might be accomplished by interpreting the wording in such a way as to equate them, or by distinguishing situations where one approach or the other is preferred. Ultimately it may be necessary to choose one over the other, however this should only be done after a thorough legal analysis of the MOU to determine which approach should override the other. In the absence of an agreed upon national level of risk tolerance, this process should also help the Board to articulate its own level of risk tolerance for the organization.

Other Stakeholders

The regulator clearly prefers one view over the other. Health Canada clearly treats safety as paramount. From the perspective of some CBS staff, cost carries little weight with Health Canada during regulatory design or approval. Accordingly, current risk management priorities (as set out in the MOU) are misaligned with the priorities of the regulator. While some difference in perspective between the organization and the regulator is natural and healthy, a misalignment between basic approaches to risk can create conflicts.

The Corporate Members are responsible for funding. While the relationship is 'arms length' when it comes to funding, the CBS Board and management feel considerable responsibility and pressure regarding budgets. Although the short term pressures have been removed somewhat by changing the governance structure to an "arms length" arrangement, there have been problems in the past with the current arrangement.

Regional Board appointees were seemingly uncertain regarding whether an additional (and potentially conflicting) responsibility to further regional interests was expected of them. And while the relationship with the P/T Contacts is generally good, that communication conduit is seen by some as being over utilized for financial matters, and under utilized for policy issues.

Eventually CBS is accountable for ensuring that the organization has the funding and capability to provide the appropriate level of safety within the Canadian blood supply. Clarity in MOU principles will help alleviate any misunderstandings regarding where that level should be. The principle 'safety first' does not readily agree with equating risk, benefit and cost, and may be the subject of misunderstandings by both sides. With the current ambiguity in definitions, CBS could be caught in the middle, determining their responsibility as putting safety first, but being funded on the basis of cost equality.

There is also a natural imbalance in perception that compounds the problem. Cost is typically easy to predict and measure, benefits are harder to estimate, and risk is the least certain of all. Timing and visibility are key. Cost is very visible early on. Benefits may or may not be visible, and there is usually an appreciable lag between the action and the benefit. Risk reduction or mitigation might not be visible at all, since the better they work, the less likely anything is going to happen at all. Accordingly, risk reduction or mitigation efforts can appear not to provide any 'value' at all, since their cost can be appreciable, and the benefit is the status quo, which can too easily be mistaken for nothing.

Clarifying whether cost, benefit and risk are equal, or whether risk holds a special status, will ensure that everyone is on the same page of the MOU (quite literally) when it comes time to justify budgets and expenditures.

Integrating Risk Management into Decision Making

As part of the assessment, documentation of a few recent and significant CBS decisions was reviewed to determine if risk management was integrated into the decision making process. As risk management implementation is still in progress, decisions that involved the Executive Management Team and Board were considered, since risk management discipline was expected to have penetrated to this level.

The decision regarding Consolidation of Testing to three existing laboratories was the one decision reviewed most comprehensively. Overall, the review showed that risks were comprehensively considered, analyzed, and factored strongly in these decisions. Numerous perspectives were sought. Potential risks were identified, facts were collected, harms and benefits were analysed. Options were developed and assessed against the risks. After a strategy was selected, alternatives were included in the implementation plan to deal with contingencies that may develop. Although implementation could not be followed up on, it appeared that plans were in effect to monitor and evaluate that process. This is an encouraging result.

While this is commendable, there is room for improvement from an integrated risk management perspective. In the course of the analysis, after much of the ground work was already completed, and after initial presentations to the Board, the proposal was analysed by walking it through the Risk Management Framework. This analysis was prepared by the Assistant Counsel who developed the Framework. The analysis was conducted using two of the preparatory documents prepared by the team. It was submitted to the rest of the initiative team in document form.

Since the Framework was under development at the time, this approach may have been unavoidable. However, to fully integrate risk management in this decision, the framework should have been referred to from the outset, and the decision process itself should continuously resort to the steps in the framework. At the least, a member of the initiative team trained in risk management should be given responsibility to apply the Framework to the decision process. And the tools within the framework should be diligently applied to each hazard identified.[58]

These steps ensure that risk is given a position of prime importance in the decision process. Running a decision through the framework after much of the process is complete can cause many risks or issues to be overlooked. The analysis tends to proceed 'inside the box' of the previous analysis. And the context can provide subliminal pressure to complete the analysis with a favourable result, since much work has already been done to support it.

As mentioned, risk management is still in implementation. However there is clear evidence of efforts to integrate risk management into operational decision making. As mentioned above, the Change Control Operating Procedure integrates a number of risk management tools to ensure that risk is dealt with.

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[58] In particular, each hazard should be plotted in the table provided, classifying them by frequency and magnitude of harm. This adds discipline by ensuring that the full process takes place, and can lead to unexpected insights.

Part of integration into decision-making includes reporting on risk management performance. This is an area that has been identified for improvement by CBS. As mentioned above current reports can be lacking in depth root cause analysis.

There are plans to improve the systems for risk management reporting. Problems with the change request process[59] have long been recognized. This process deals with changes to the operating procedures. It typically has a significant backlog. The number of change requests in the system, duplication across change requests, the lack of a speedy system or process for rationalizing them, as well as delays in validating and approving them on the part of the regulator, create significant additional delays in this process.

CBS has made progress in risk management systems. A number of performance reports that support risk management have been made available through the development of the E-z track system. CBS is currently exploring options for an integrated risk management information system that can help deal with risk issues in a more comprehensive fashion. This would be a positive step. The plans are still in development, and are currently at the information gathering stage.

Building Organizational Capacity

Ultimately, human resources are the defining factor in risk management. CBS has come a long way in developing organizational capacity for their risk management model of the future. We feel that this will continue.

On creation of CBS, much of the staff was inherited from the Canadian Red Cross, and along with them came their capacities and culture. The CRCS was founded for emergency response. The culture was heavily humanitarian and charitable. Hiring tended to reflect that. Staff was good at multitasking, since that is valuable in responsive situations. Their blood services grew out of this environment.

From its inception, CBS realized it had to be proactive. Planning and preparation were emphasized, and control of internal processes became the mechanism for reducing risk. They realized that specialization was more important in this proactive environment. This was emphasized in training and hiring. Professional management capacity was built to deal with the new organization and culture.

This is a massive culture change, and it is still continuing. The challenge is to maintain the momentum.

CBS continues to work to build risk management principles into competency profiles and job descriptions. This is built into the implementation plans. This can be expected to take some time, particularly in a unionized environment. Training already focuses on quality, and broader risk management development will be built into this training as implementation proceeds.

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[59] This is being encompassed into the Change Control Operating Procedure discussed above.

The development of tools and processes for risk management is part of capacity building. This is taking place at CBS. Details regarding development will be discussed in the next section.

6.3.4 Practicing integrated risk management

A Common Process

There should be a common, continuous process for understanding, managing, and communicating risk. Progress toward this goal continues. CBS certainly has processes for managing risk. The control systems and mechanisms described earlier in this chapter all support risk management.

What is still to be achieved is the rationalization of risk management mechanisms into a common process. Since this is a key theme to risk management implementation at CBS, and that implementation is in relatively early stages, the most value can be provided by commenting on the plans and models that have yet to be implemented.

The CBS Risk Management Framework

The CBS Risk Management Framework is under revision. It will be useful to compare this model with the model in the TBS Integrated Risk Management Framework.

The two models are similar. As is common in comparing good risk management models, similar steps are contained in both, however the CBS model combines the 9 steps of the TBS model into 7. This is not an issue, so long as the same basic process is followed in each. A comparison between the two shows that the CBS model is generally aligned with best practices, but could be fine-tuned.

Step 1 of the CBS model, Identification of Issues and Collection of Facts/Context is comprehensive, and agrees well with the TBS model. A comprehensive list of stakeholders, as well as information gathering tools is provided. A good deal of rationale is provided to back up the need for these tools. A minor comment is that this part of the text begins to read like a report or plan for change rather than a framework. It is suggested that the wording be revisited and edited to make certain references less time-sensitive, so that the framework does not need frequent updating.[60] In future it should become a framework for ongoing risk management, rather than a framework for risk management implementation.

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[60] An example is the reference to the pending implementation of the MAK system.

CBS does well to adapt their model to their mission and circumstances, by including the engagement of partners and stakeholders as a central and continuing theme across all steps. This appropriately turns the focus away from the internal environment (unlike the TBS model) and towards the external, where the biggest impacts of risk would be felt.

Step 2 of the CBS model, Assess Harms and Benefits, combines two Risk Assessment steps of the TBS model (Assess Key Risk Areas; Measure Likelihood and Impact). This step includes choosing tools, and a common tool is illustrated: a frequency/magnitude table. This table includes an extra category: 'Unknown'. This is very appropriate, considering that many of the threats to the blood supply arise out of the unknown, or are of uncertain frequency or impact. Consideration ought to be given to the position of the 'Unknown' column. It is currently placed at the end of the High/Medium/Low sequence, which might suggest that unknown threats can be ignored (since they are lower than Low). This column could be moved to the other end of the chart, or separated from the other columns by a double line, to better distinguish it.

A similar table is provided in the TBS model. One difference is that the TBS model places entries in the boxes to suggest risk management actions that might be considered, depending on the context. This might be considered for the CBS model. Care would have to be taken to ensure the actions are appropriate to CBS, and that they are clearly suggestions that should not be rigidly applied[61]. As a suggestion, entries under the 'Unknown' categories could reflect the need for research, which also serves to emphasize this important part of the CBS mandate.

A second table is provided in comparison to the CBS table. While this gives justification or credit, we would suggest removing it, since its presence is unnecessary to CBS. A comment might be added that this type of tool can be modified or simplified to suit the circumstances of a particular function within CBS.

Step 3 of the CBS model, Identification and Analysis and Prioritization of Risk, corresponds to Step 4 of the TBS model (Ranking Risk). It is a natural continuation of the previous steps. This is where risk tolerance is considered, and appropriate consultation is again indicated. It might be appropriate to suggest that a list of risks be developed for each analysis, where the corresponding harm and benefit ratings can be entered beside each, along with a column for risk tolerance (acceptable/not acceptable, and by whom).

Step 4 of the CBS model, Identification and Analysis of Options, corresponds to Steps 5 and 6 of the TBS model (Setting Desired Results; Developing Options). It is noted that the MOU's concept of equality of risk, benefit and cost is cited here. Obviously, this should be rationalized with the principle of paramountcy of safety, as discussed above.

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[61] For example, medium frequency, low impact harms to donors might not always be acceptable, since they would deter repeat donations.

It might be useful at this point to document the criteria considered for development of options. This tends to broaden the thinking of those involved, and ensures that analysis takes place, rather than jumping ahead into ideas for solutions. Listing criteria at this stage helps in the later step in choosing a solution.

This section should specifically note that different options can create new risks. It should suggest that these new options should be assessed by reviewing the previous steps in the framework with the new options in mind, to identify and analyze the new risks inherent in these options.

Step 5 of the CBS model, Selection of a Risk Management Strategy, corresponds directly to Step 7 of the TBS model. The framework should note that the criteria used and rationale for the decision should be documented appropriately for future reference. This is helpful in the later stages of the process.

Step 6 of the CBS model, Implementation, corresponds directly to Step 8 of the TBS model. The framework should specifically note that implementation is usually the greatest challenge in any initiative. It should specifically state that all but the simplest implementations should be planned. There is room for internal input to implementation planning. Involving all groups impacted by the change in the planning is a best practice, though the need for expediency may often prevent this.

Step 7 of the CBS model, Monitoring, corresponds to Step 9 of the TBS model. While the diagram in the CBS model refers to the need for ongoing evaluation, the text focuses on monitoring. Specific reference should be made to the need to report on the performance of the change, re-evaluate it regularly, and to initiate adjustments as appropriate. This process can be conducted using the framework itself as a guide for considering changes.

CBS Change Control Operational Procedure

An overview of the Change Control Operational Procedure was provided above. It provides a process for change, and includes a risk management framework and tools. But as currently drafted, it is broad in scope. In its objectives, it is to be used for “changes that impact any CBS operation”. Its scope includes “all functions under the control of Canadian Blood Services”. And the criteria for approval levels include a change that ‘affects strategic direction of CBS”. Taken as a whole, these comments could be interpreted to mean that any and all business changes must follow this process.

Confusion could exist between this procedure, and the procedures set out in the Risk Management Framework. Both do not yet cross-reference each other, and tools and terminology vary, increasing the likelihood of confusion. The situation could develop where different CBS staff could apply different frameworks to the same processes or activities. The two should be rationalized, to ensure a common approach.

One portion of the Change Control Operational Procedure is cause for concern. Attachment VII provides "Risk Management – Decision-making models to use in Risk/Benefit Assessment". These were derived from a management publication (duly cited on the document). As generic tools developed for generic organizations, they may not suit the particulars of CBS, and should be adapted appropriately.

For example, "four essential questions" are posed for risk decisions, but these focus on the acceptability or affordability of loss to the *organization*. Bearing in mind the CBS mission, its stakeholders are the foremost concern, and the consideration should at least be shared here. A four-box frequency/severity grid is provided. It only allows rankings of high and low, which may be overly subjective for the CBS situation. It then suggests results which may not necessarily be appropriate. For example, a risk that is low in severity but high in frequency is classed as 'Inconsequential'. In reality, a low severity incident involving donors that occurs frequently is certainly not inconsequential to CBS risk, since repeat donations are extremely important.

This tool may have been developed with the private sector in mind. Other questions in the document tend to focus on the affordability of risk-taking. CBS tends to focus on the opposite approach; it is a risk-minimizing organization. The tone of the document may send a message of tacit approval of risk-taking activities, which may not be in the organization's best interest.

There are some very useful aspects to this tool. It discusses five critical aspects of loss that are useful in risk analysis, including duration and permanence of the loss. These concepts and questions might be adapted for use in the CBS Risk Management Framework itself.

A comprehensive process for change requests is set out in the Operating Procedure. Roles and responsibilities are made clear, which is of critical importance. However, it is possible that the assignment of responsibilities may create a disincentive to risk identification at the 'front lines' of CBS. By all accounts, CBS staff members are dedicated and hard working. They are busy, and paperwork is an issue in the workload. The responsibility for completing much of the change request paperwork, including the priority analysis, root cause analysis, rationale and justification of the change, and the detailed risk analyses, falls upon the 'change initiator' (with support from the change manager). This involves a lot of time and work (the Operating Procedure is 30 pages long). Since the 'change initiator' is the employee who identifies the need for change, there is a definite fear that busy employees could be tempted to 'look the other way' when a risky situation presents itself, rather than to face the prospect of completing all of the paperwork. The roles and responsibilities should be reconsidered in light of this.

It should be noted that the other tools in the Attachments (such as the Hazard Analysis Tool) have been specifically tailored to CBS needs. These are potentially very good tools for risk analysis. They should be mapped to the steps in the Framework, and specifically reference the Framework in appropriate places.

Recommendation #95: Sending a common message for risk management is important, particularly in an implementation. A common approach should apply, so that all risk management activities have a universal 'feel' to them. Tools used for risk management should tend to reflect the approach in the framework. This reduces the potential for confusion over risk management, ensuring that people know what tools they are using, and why. It is recommended that CBS design the Risk Management Framework as a common template from which to derive others. CBS should try to make all other risk management frameworks within the organization 'look and feel' similar. Certainly risk management tools must be tuned to suit the specific needs of particular functions or processes. However, this is best accomplished by adding additional information to a common template wherever possible. When it is seen as preferable to deviate from the common template (e.g. to simplify the table), ensure that such deviation makes practical sense, is approved by the Risk Management Director, and specifically note that this is a deviation in the functional framework itself. Specifically include a reference to the CBS Framework in the tool (perhaps by footnote). Since the CBS Framework is still undergoing revision, it could be expanded or modified to be consistent with some of the processes and tools used elsewhere in the organization. Another approach would be to revisit the tools themselves, by specifically mapping various steps in the tools to the Risk Management Framework. This could ensure consistency of application, since those using the tool can better understand which step in risk management the tool is designed to support.

Recommendation #96: It is recommended that a common risk management language be developed by CBS. CBS should determine where terminology and language is incongruent, and resolve these. This should apply to terms within different risk management tools, and also to terms commonly used that have different meanings or connotations within the organization. CBS should add a glossary of terms and concepts to the framework and standardize risk management tools along with the framework, displaying a 'common front'. CBS should communicate early and often, using the terms consistently.

Integrating Results at All Levels; Communication and Consultation

Although plans exist, it is too early to determine how well risk management will ultimately be integrated into CBS. Interviews have revealed that there is a good awareness of the existence of a Risk Management Framework, and that tools such as the Hazard Analysis Tool are used across the organization.

As discussed above, there is a need to send a consistent message horizontally across different functional units. Plans exist to include representation from different functional units on the Risk Management committee. Management is committed to involving people from all functional areas in the planning.

Risk management should also be integrated across geographical units. This is currently an area of concern. Different centres across the country have followed different paths. In the past they operated very independently . While standardization of practices is a common theme at CBS, it is a work in progress. For example, Centres differ in philosophy over Centre Operation Procedures (COPS). Some Centres use them only as necessary exceptions to the Standard Operating Procedures (SOPs), while others appear to write a COP to cover anything that is not mentioned in the SOPs. The proliferation of COPs has acted as a barrier to change, since a process tends to remain 'established', and they can differ significantly between Centres.

Management has recognized this as a challenge. The Executive Management Team has made a point of travelling to the Centres on a regular basis, to help unify the focus of CBS. Some executives make a point of holding open sessions with Centre staff while they are there. Accounts from both the Centres and Head Office agree that communication is much improved, and they also agree that it can still be improved further. This commitment is a positive sign.

Particular attention will have to be paid to ensuring that risk management penetrates the Centres in a standardized manner. A clear and consistent approach to risk management is advisable, using standard messages, models, terminology and training. To ensure that these messages have the same effect, a survey should be taken of the state of understanding and readiness for risk management across the country. In addition, it will be important to ensure monitoring and feedback of the state of the implementation as it proceeds, and to respond to any problems.

Recommendation #97: To fully integrate risk management into decision-making, it is recommended that CBS apply the framework to the decision making process as it progresses. CBS should break the Framework out into its individual Steps, and ensure that each step is individually documented at the corresponding step in the decision process. Step 1 can be documented early on in the process, since that is where it naturally fits. Other steps can be applied and documented at their appropriate stages. As each step proceeds, CBS should be sure to review previous stages, and repeat them if necessary, since each step can provide new information that may not have been considered for a previous step. CBS should document these updates as required.

Ensuring continuous risk management learning

As discussed previously, the groundwork is being laid for ongoing risk management learning once implementation is complete. The early signs are encouraging. The management team is committed to risk management, and is prepared to demonstrate leadership here.

The culture of the organization is changing. The organization has always relied on learning and training, but they are becoming more specialized in their roles. Plans exist to incorporate risk management into their competency profiles. Targeted training is anticipated to meet the need for specialized training.

Recommendation #98: It is recommended that CBS use the framework (or appropriate tools) like a template, methodically applying risk management steps and processes. Only skip over particular steps when there is good reason to do so. The tools should be applied by default, and exceptions should be justifiable. As a specific example, the frequency/magnitude grids should be used wherever possible, and the results documented. There are two main reasons for the need for discipline here. Actually completing these tools ensures that the full process is carried out. It reduces the chances that an important factor could be misjudged or overlooked in haste. And the results can sometimes be surprising, which will raise new issues, or new questions concerning the accuracy of the assessment.

Secondly, discipline is important in the earliest stages of risk management implementation. Use of the tools models that behaviour for others. It shows that this is part of the job, and will encourage others to follow the process. It makes it more likely that risk management will catch on in CBS, and will not be seen as a 'passing fad' imposed by management.

Recommendation #99: To complete an organization's understanding of risks, it is recommended practice that each of the organization's exposures/risks be subjected to "stress-testing". Worse case scenario analytics allow an organization to assess its preparedness, identify the effects of a risk event, risk correlations and respond accordingly through appropriate amendments to the risk management infrastructure. "Stress-testing" can be viewed as a "fire drill" designed to assess the robustness of the existing risk management infrastructure to existing or hypothetical risks. In effect, fire drills are meant to ask all the difficult questions – ahead of an event. It is recommended that CBS incorporate this approach into its risk management process.

Recommendation #100: It is recommended that CBS send the message that risk management is the future, from the top. CBS should ensure that all managers model the correct behaviour, by visibly using the framework, models and tools.

Recommendation #101: There are a number of initiatives underway and CBS must ensure that risk management receives appropriate attention. Risk Management must be integrated, coordinated and communicated along with the other changes. It is recommended that CBS obtain change management support, either internally or externally and ensure that change management resources are dedicated to risk management.

Recommendation #102: It is recommended that CBS survey the staff on their understanding and readiness for risk management. Seek their input on plans, and involve them wherever possible. Standardize the approach across Centres, but ensure that each Centre is getting the same message by monitoring and following up on feedback.

Recommendation #103: It is recommended that CBS integrate the approach to risk management with other activities and training. CBS should ensure that risk management is seen as part of the job. There is a need to stress discipline in the risk management process and show staff that documenting is for their benefit as well. CBS should seek a balance between education and audit. Audits should be a vehicle for learning, rather than a technique for punishment.

Recommendation #104: It is recommended that CBS ensure that ongoing review of the risk management framework is carried out. The following suggested Risk Management Best Practices provide guidance for ongoing review of the risk management framework:

- Get top management and Board buy-in
- Recognize and understand the politics of the organization
- Involve similar groups in risk management planning
- Involve frontline staff and volunteers
- Balance compliance and risk management
- Make risk management a Senior-level management responsibility
- Create awareness
- Promote a philosophy that education is better than punishment
- Establish a common risk management language

7. Summary of Recommendations and Suggestions for Implementation

7.1 *Prioritization of Recommendations*

This chapter provides a summary of all of the recommendations that have been documented in the previous chapters. All of the recommendations are important but clearly it is not feasible to implement all of the recommendations at the same time. Therefore, an attempt has been made to prioritize the recommendations. Priority has been assigned based on the consulting team's view of the urgency of the issue to be addressed, the risks of not addressing the issue in a timely manner and the potential for early cost savings. Each recommendation has been grouped into one of the following four priority categories:

Immediate:	Recommendation should be acted upon immediately (within 3 months)
High:	Recommendation should be acted upon within 3 to 6 months
Medium:	Recommendation should be acted upon within 6 to 12 months
Low:	Recommendation should be acted upon within 12 to 24 months

The table below is a high-level summary of the recommendations by priority group. The recommendation numbers used in the body of the report are shown in square brackets as a cross-reference. The recommendations have not been prioritized within each of the four categories. The table also indicates whether lead responsibility for *initiating* action on the recommendation rests with CBS or the P/T Members. However, it is important to stress that many of the recommendations require collaboration and/or input from CBS, the P/T Members and perhaps other stakeholders as well.

Exhibit 7.1 – Prioritization of Recommendations

Recommendation	Lead	
	CBS	P/T Members
IMMEDIATE PRIORITY (< 3 MONTHS)		
• Communication strategy for P/T Members and other stakeholders (including communication about Transformation) [4, 13]	✓	
• Clarification of the role of: Members, P/T Ministries of Health, P/T Contacts, lead Ministry, CBS Board of Directors, CBS Executive Management Team [7]		✓
• MAK Progesa business case [12]	✓	
• Program Management Methodology for the Transformation initiatives [14]	✓	
• Member briefings on regulatory changes [19, 20]	✓	✓
• Reduce blood bag wastage rate [24]	✓	
• Development and dissemination of Utilization guidelines for IVIG and other high use fractionated products in conjunction with National Technical Working Group, dissemination of results of the IVIG Consensus Conference and enforcement of utilization management programs in hospitals [31]	✓	
• Working capital issues (stop use of restricted funds, investigate line of credit, finance working capital, link to strategic issue of product utilization) [36, 37, 38]	✓	
• Feasibility assessment of virtual warehouse supplier arrangements to minimize inventory [39]	✓	
• Assess staff requirements for Finance function [53, 54]	✓	
• Implementing purchasing and accounts payable process efficiencies [55]	✓	
• Explore with Health Canada creation of pre-approved procedure for break, fix and maintenance IS procedures [69]	✓	
• Review SAP licensing agreement and benchmark per seat costs [75]	✓	
• Continue international benchmarking of labour hours per unit and other indicators that may identify potential efficiencies [85]	✓	
• Reduce blood component discard rates [87]	✓	
HIGH PRIORITY (3 TO 6 MONTHS)		
• CBS board composition (filling of gaps in expertise) [2]	✓	
• CBS formal board evaluation program [3]	✓	
• Improved communication between CBS and P/T Contacts to enhance development of budget information and preparation for the annual meeting with Members [5, 47]	✓	✓
• Increased time for meetings between CBS and Members		✓
• Statement of vision (i.e. future directions for CBS scope of services, role in R&D etc) [8, 28]		✓
• Change management for the transformation project [15]	✓	
• Complete business cases for priority transformation initiatives and share with PT Contacts including capital plan for building of new testing facilities [16]	✓	
• Increased standardization – criteria for Centre Operating Procedures, patient services, demand forecasting, budget management, unit cost targets [17]	✓	
• Monitoring of donor recruitment costs [23]	✓	✓
• Monitoring of administration/overhead, travel expenses and professional	✓	✓

Recommendation	**Lead**	
	CBS	**P/T Members**
fees, particularly for the Change Control and System Validation initiatives [25, 26]		
• Address budget deficits in regional centres and plasma centres [29]	✓	
• Formulae for product costing (unit cost for each type of blood component, full costing model for fractionation including plasma centres, patient services cost recovery model) [30, 46]	✓	
• Evaluate opportunity to implement SAP inventory management module across all inventories [40]	✓	
• Multiyear budget submission improvements and piloting of reporting information by functional area [42, 43, 44, 48, 49, 50]	✓	✓
• Volume or activity-based budgeting [45]		✓
• CBS financial reporting improvements (internal and external reporting) [51, 52, 59, 60]	✓	
• Consider implementation of employee time-entry [58]	✓	
• Establish IS Control Project Management Office [62, 63]	✓	
• Review PC platform purchasing options [65]	✓	
• Implement internal chargeback or cost allocation mechanism to control telecom and office equipment costs [66]	✓	
• Continue to review IS disaster response capability and consider adoption of an accepted framework [68]	✓	
• Complete "strategy map" to ensure that indicators are identified for all measures and recommended new indicators and improved targets are included [76, 77, 78]	✓	
• Cost targets for Centres [79]	✓	
• Re-evaluate NAT testing [82]	✓	
• Shift hospital knowledge boundary (e.g. collect hospital indicators and information to improve discard rates and inventory management) [83]	✓	
• Re-evaluate CBS' role in facilitating inventory management of blood and blood products throughout the blood system, including hospitals [88]	✓	
• National Customer Service strategy for hospitals [91]	✓	
• Risk management recommendations [92 to 104]	✓	
MEDIUM PRIORITY (6 TO 12 MONTHS)		
• Review MOU [1]		✓
• Policy framework in accordance with the MOU, including clarification of how to balance safety and affordability [9]		✓
• Policy and operations-focused Research and Development [10, 27]	✓	
• Continue hosting stakeholder forums related to policy development [11]	✓	
• Explore adoption of a set of uniform national standards [21]	✓	
• Initiatives for education of health professionals involved in blood banking, transfusion medicine, treatment of blood-related diseases, etc. [22]	✓	
• Process for sharing best practices from provincial blood committees [32]	✓	
• Establish a new, or use an existing, expert advisory group to help develop the annual fractionation budget [33]	✓	
• Examine UBMDR funding model [34]	✓	
• Contingency Fund Policy [41]	✓	
• Identify additional benefit opportunities with SAP [57]	✓	

Recommendation	Lead	
	CBS	**P/T Members**
• Performance measures for the finance function [61]	✓	
• Review IS change management and training plan [64]		
• Review and realign administration and operations management role within IS [67]		
• Eliminate FPIS and include donor scheduling and call list generation in ESS [71]		
• Revise resource scheduling model to reflect actual clinic capability [72]		
• Explore functionality to be able to telemarket to donors outside of clinics they have frequented in the past [74]	✓	
• Plain language assessment of the donor screening form and assessment of interactive video approaches for donor screening [80, 81]	✓	
• Reassess location of plasma centres [84]	✓	
• Comparative analysis of cost of different collection models (e.g. permanent clinics, mobile clinics, bloodmobile) [86]	✓	
• Strategies to increase donations from Canada's multicultural community [89]	✓	
• Investigation of hospital concerns about transport services that were identified in the hospital survey [90]	✓	
LOW PRIORITY (12 TO 24 MONTHS)		
• Increased Standardization – capital plan for Centre facilities and equipment and ongoing review of potential consolidation opportunities [18]	✓	
• Assessment of single vs multiple suppliers [56]	✓	
• Address time lag in getting clinic results from BLIS [70]	✓	
• Explore use of mobile technologies or expansion of remote access capabilities as part of PDSI replacement [73]	✓	

7.2 Suggestions for Implementation

The recommendations summarized above are many and they cover a variety of aspects of CBS governance and operations. Successful implementation will require a practical and effective implementation plan. This section offers a suggested approach to implementation. However, to be effective, the approach must recognize the specific needs and limitations of the organizations involved. When and how implementation unfolds will depend on many factors including the resources available, competing priorities and the degree of commitment from the Members and CBS.

Implementation should be led and coordinated by the BC Ministry of Health in their capacity as lead Ministry for CBS. This role would include:

- Establishing a small committee of P/T representatives to review the report, ensure that the required process for approval of the report is followed and decide if all or some of the recommendations should be pursued

- Preparing a communication plan for release of the report, including a briefing with CBS
- Delegating responsibility for following through on recommendations to CBS and P/T representatives as required
- Preparing an implementation plan that outlines who is leading each recommendation, the expected completion date and any implementation issues (e.g. cost implications)
- Establishing an accountability process to monitor progress on the recommendations (e.g. monthly or bi-monthly teleconference calls)
- Providing regular (e.g. quarterly) updates on the implementation of the report recommendations to the P/T contacts and the Members
- Six months after the approval of the final report, a meeting of the P/T Contacts and CBS should be convened to discuss the progress being made with respect to the report's recommendations.

CBS has lead responsibility for the several recommendations in the "immediate priority" category. It is important that these recommendations are acted upon as soon as possible. The lead Ministry should ask CBS (through the Board Chair or CEO) to identify a member of the Executive Management Team to lead each of the top priority recommendations. CBS should provide the lead Ministry with monthly updates on the progress of these recommendations. In addition, the issue of financing the working capital has financial implications for the Members. The lead Ministry should convene a special meeting or teleconference call for the Members to review and approve the working capital financing options. Detailed information to support Member decision-making on this issue should be provided by CBS in advance of the meeting (a draft should be submitted to the lead Ministry for feedback before the final version is circulated to all of the Members).

Many recommendations will fall to CBS for follow-up. Since the review was commissioned by the Members, ultimate responsibility for implementation of the approved recommendations should rest with the CBS Board of Directors. The lead Ministry should ensure that the Board Chair is briefed on the final report and the Provincial/Territorial implementation plan (e.g. a meeting involving the lead Ministry's Deputy Minister of Health, P/T Contact, CBS Board Chair and CBS CEO). CBS will need their own internal implementation plan. A senior individual within CBS should be assigned to implement each recommendation. Progress reports on the review recommendations should be a standing item on the agenda of each meeting of the Executive Management Team and the Board of Directors.

Some recommendations will have cost implications for CBS. Within a month of approval of the final report, CBS should prepare a summary of the anticipated cost impact of the recommendations, including which costs can be covered with the existing budget, which recommendations require additional one-time funding and what cost savings are expected. This information should be submitted to the lead Ministry.

7.3 Complete List of Recommendations

The following is a complete list of the recommendations contained in the report:

Recommendation #1: The MOU is a critical guiding document for the national blood supply system. Unfortunately, the document includes a number of ambiguities that have contributed to lack of clarity in terms of roles and expectations. It is recommended that the Provincial/Territorial Ministers of Health and Health Canada initiate a process to clarify the ambiguities in the MOU and ensure that the current and future realities are reflected. A desired outcome would be a set of uniform priorities regarding safety, benefits and costs. If the relative weights of these factors are to vary depending on circumstances, these should be clearly spelled out. Ideally, the MOU review process should follow the proposed development of a vision (see below) so that the MOU is reflective of future directions. There are a number of optional approaches that could be taken: 1) the Members could initiate a review of the MOU and open a dialogue to change the wording of the ambiguous sections, 2) the Members could execute an addendum to clarify the ambiguous issues, or 3) some other form of common agreement between the parties could be reached to address specific issues that are currently unclear (e.g the policy framework might accomplish this). Reviewing and amending an inter-provincial MOU is a significant undertaking and the Members should seek legal advice on the most appropriate approach.

Recommendation #2: Currently board members are selected based on geography as well as their expertise in business, scientific, medical, technical or public health matters. When filling future vacancies it is recommended that Members consider recruiting individuals with experience in corporate law, information technology and transfusion medicine.

Recommendation #3: It is recommended that CBS complete the proposed development and implementation of a "formalized" Board evaluation process.

Recommendation #4: It is recommended that CBS develop a detailed Stakeholder Communications Plan that recognizes the Members as key stakeholders. The Stakeholder Communications Plan should include:

- A formal and ongoing government communication strategy that would include communications with the Ministers, Deputy Ministers, P/T Contacts, Federal officials and other key government stakeholder groups. This will be particularly important during implementation of the Transformation Project which will have varying degrees of impact on different provinces.
- Protocols for Board of Director communications with senior Provincial/Territorial officials. These protocols should take advantage of Regional Director reporting relationships and access to Ministers of Health. The communications protocols should also acknowledge that all CBS Directors should have access to Provincial/Territorial officials. The nature of the communication between regional

directors and Ministers of Health should respond to the needs of the Ministers but would likely include updates on CBS issues and projects of interest to the Minister and solicitation of advice from the Minister on provincial factors to take into account in the corporate planning process. The protocols should also set expectations on the frequency of reporting to Ministers (e.g. twice per year).

Recommendation #5: The Annual Meeting between CBS and the Members is perhaps the single most important event for the CBS Board and EMT. Preparatory activities such as identification of coaches, intelligence gathering, identifying potential questions and hot spots, audience analysis, presentation skills, etc. are critical. The goal is for CBS to go to the Annual Meeting with a clear idea of the Members needs and armed with the specific information the Members require. Effective communication between CBS and the P/T Contacts will provide advance notice of the interests and likely receptivity of Members to what CBS wishes to present and or have approved.

Recommendation #6: To improve communication between CBS and the Members, it is recommended that Members identify ways to expand the length of the meeting time with CBS and/or increase the number of meetings held per year. The recent establishment of the Deputy Ministers' Policy Committee on Blood is a good start to building a better relationship.

Recommendation #7: It is recommended that the CBS Board and Corporate Members engage in a process to clarify the respective roles and responsibilities of Corporate Members (both as Members of CBS and as Provincial/Territorial Health Ministers), Deputy Ministers, the lead Ministry, P/T Contacts (a generic job description should be created), the CBS Board and the CBS Chief Executive Officer. This review of roles and responsibilities should give special consideration to clarification of roles and expectations with respect to utilization management. The statement of roles should emphasize a partnership between the Provincial/Territorial Ministers and CBS that recognizes that is the responsibility of the Ministers, not CBS, to manage utilization at the hospital and physician level. CBS can however, play an important role in research, education, guideline development and evaluation of utilization practices.

Recommendation #8: Discussions with stakeholders revealed a lack of a common view of where the organization is and should be heading in the future. It is recommended that the CBS Board and Corporate Members engage in a facilitated process to renew the CBS vision and describe the future role and scope of CBS. Clearly, there are a number of directions that could be pursued. Some of the directions that have been suggested by stakeholders include:

- Reduce size and scope of CBS to be strictly a producer and distributor of blood and blood components. This direction would consider such strategies as divesting the distribution of fractionation products, divesting patient services, outsourcing certain infrastructure functions (e.g. payroll, IT), shifting research and development and public education roles to other players, and leaving utilization issues to the provinces/territories.

- Enhance the size and scope of CBS through growth and diversification. Strategies that would take prominence with this direction might include working towards goal of plasma self-sufficiency, enhancing CBS' role in utilization management, increasing CBS' role in research and development and increasing CBS' technical leadership in transfusion medicine.

The vision must respond to the needs of the key stakeholders. It should reflect a customer-facing posture that places greater emphasis on utilization issues and hospital linkages. The review team does not support a reduction in scope that is based on divestment of the fractionation business because the MOU defines blood as including alternatives and commercial products. Also, it is not evident that there is an organization better equipped to take this on or that setting up a stand-alone fractionation operation would improve effectiveness or efficiency. Internal operations however, should be as lean and efficient as possible. As emphasized throughout this report, the review team favours an enhanced role for CBS in development of utilization guidelines and education initiatives.

Recommendation #9: The MOU implies that it is the responsibility of the CBS Board to develop operational policies within a framework established by the Corporate Members. The policy framework has never been developed and there have been few opportunities for productive policy discussion. Therefore, it is recommended that the Corporate Members initiate a process to create a policy framework that would guide policy development by CBS. The framework should include direction to CBS on how to balance safety and affordability in the blood system and what level of safety/risk will be acceptable for Canadians. Development of the policy framework should be informed by public dialogue, research and comparisons with blood systems in other jurisdictions.

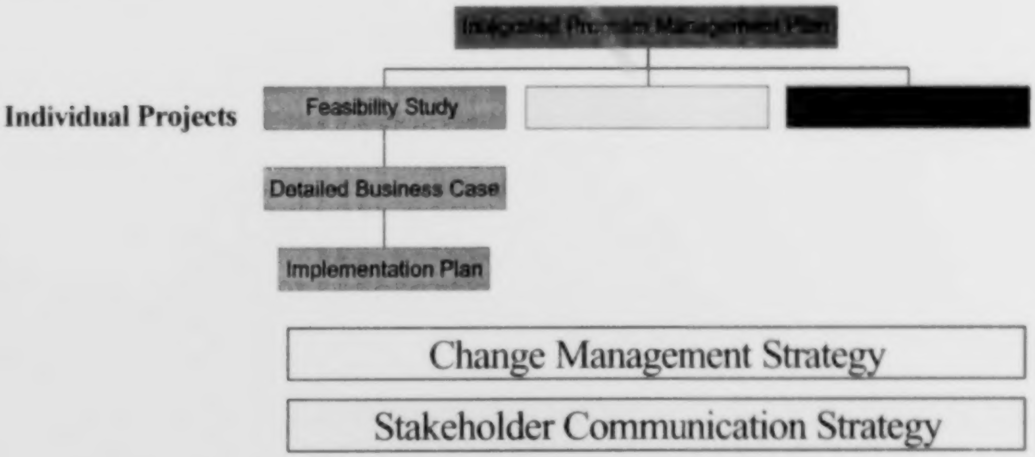
Recommendation #10: It is recommended that Members request CBS to use a portion of their Research and Development funds to conduct research of a policy nature. For example, research on how other countries have dealt with key policy challenges such as balancing safety and affordability and establishing a level of risk tolerance.

Recommendation #11: It is recommended that CBS continue to convene regular (e.g. annual or semi-annual) forums to gather stakeholder input that will assist CBS in developing strategic policies. CBS has conducted forums in the past. The difference here is the link to policy development. CBS would be accountable for identifying a clear policy goal for each forum, disseminating forum proceedings in a timely manner and following through with policy development. Key policies would be submitted to the Members. Some of the pressing policy issues that should be considered include plasma self-sufficiency and utilization of fractionated products (particularly IVIG and Recombinant Factor VIII). It is important to note that a policy discussion on plasma self-sufficiency should be informed by a thorough identification and analysis of plasma costs (both production and purchase) and fractionated product utilization guidelines that will help to determine the level of demand that should be forecasted.

Recommendation #12: CBS does not have a completed business case for implementation of MAK Progesa because the decision to implement MAK was made by the Canadian Blood Agency before CBS was formed in 1998. It is recommended that CBS expeditiously complete the business case for MAK that is currently under development.

Recommendation #13: It is recommended that CBS develop a Transformation Communication Strategy for Corporate Members and CBS staff/volunteers that uses consistent language and provides for regular updates on project status. This could be part of the Stakeholder Communications Plan referenced earlier. As part of the strategy, CBS would clarify and communicate to the Corporate Members and the P/T Contacts at the earliest opportunity, how each of the Transformation initiatives that is being planned will be financed. This must include a description of operational and capital cost requirements and the projected timing of both funding investments and cost savings.

Recommendation #14: The planning phase for Transformation has been long and many of the projects identified are intended to be organization-wide. Managing the complexity and project interdependencies of any national, large-scale initiative is a challenge. It is recommended that CBS implement a rigorous program management methodology for Transformation as soon as possible. The program management methodology should include development of an integrated project plan that shows how all of the projects fit together, costs, benefits, phasing and interdependencies.(see below)


Integrated Program Management Plan
Individual Projects
Feasibility Study
Detailed Business Case
Implementation Plan
Change Management Strategy
Stakeholder Communication Strategy

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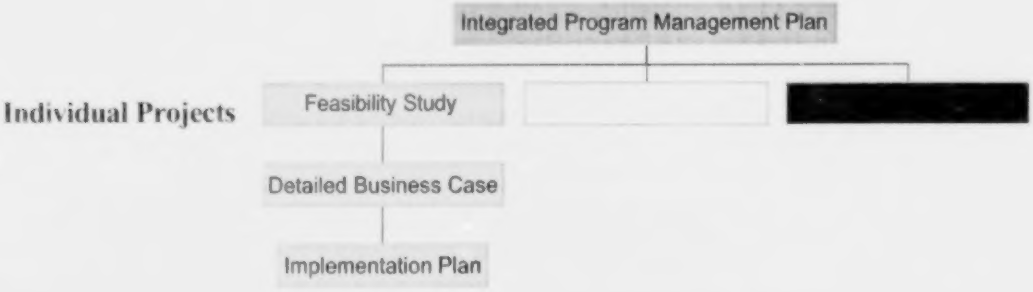


Change Management Strategy

Stakeholder Communication Strategy

Recommendation #15: CBS has undergone, and continues to undergo, a great deal of change in many areas. Staff are change weary and they will require a great deal of support, training, information and communication to make the Transformation Project a success. It is recommended that CBS implement an organization-wide Change Management strategy for the Transformation Initiative as soon as possible. Ideally, a dedicated staff position should be identified to lead the Change Management program. [It was noted that during this review, recruitment was underway for a Manager of Organizational Development at Head Office whose role will include Change Management, among other duties.]

Recommendation #16: While CBS has provided business cases for some of the Transformation Initiatives, it is recommended that business cases be developed in a timely manner for all projects that are being pursued. Each business case should include at least the following information:

- Full description of the initiative
- Timeframes for planning, implementation and evaluation
- Description of costing methodology and planning process
- Application of the cost, benefit, risk framework mentioned in the MOU
- All costs (planning, implementation, ongoing, capital)
- Timing of cost outlays and cost savings
- Expected benefits and how they are to be achieved and measured (e.g. cost savings, safety impact, supply impact, efficiency gains, automation improvements, staffing impact, donor impact)
- Performance measures and targets
- Implications/risks (e.g. product supply impact, staffing impact, donor impact, regulatory impact)
- Financial and operational performance metrics to be used for the initiative

Information should also be provided on the impact in the province of each member.

Recommendation #17: Although there has been improvement in the establishment of a national model, there is still significant variation across the regional Centres. This variation exists in the scope of services, operating procedures and the nature of equipment and facilities. It is recommended that CBS continue its efforts to increase the level of standardization in the Regional Centres. This should include:

- Reducing and standardizing patient services
- Developing and enforcing more rigid criteria under which Centre Operating Procedures should be developed
- Developing a standard template for demand forecasting for use by the regional Centres
- Continuing to maximize consolidation opportunities over the long-term based on evidence-based assessments of costs, benefits and risks. A number of consolidation initiatives have been implemented or are planned; continued evaluation of the

benefits and savings from these initiatives will help to identify additional opportunities (e.g. further reduction in consolidation sites or additional functions to consolidate).

Recommendation #18: According to CBS, many Centre Operating Procedures exist because of a lack of standardization of equipment and facilities. It is recommended that CBS develop a capital plan that includes a long-range strategy to standardize equipment and facilities as much as possible within capital cost constraints that may be imposed by the funders/Members.

Recommendation #19: Health Canada is presently reviewing and revising its regulatory framework. In situations where a new regulatory requirement is in the works that will have major cost implications, CBS should routinely prepare a detailed briefing note for Members on the process, anticipated changes to the framework, the expected impact on CBS and any action that needs to be taken by CBS or the Members.

Recommendation #20: It is recommended that the Members convene a meeting with Health Canada for a presentation on the regulatory framework and discussion of how to minimize the burden of the regulatory process for CBS while respecting safety considerations.

Recommendation #21: In order to further improve uniform best practices and predictability among Canada's blood Centres, a national set of standards applied to all blood facilities would be desirable. They would be divided into two categories: 1) Laws defining required practices for regulated products and processes; and 2) Standards defining ideal or precatory best practices for products and processes not mandated by law. It is within the second of these categories that CBS should be proactive. Ideal and uniform standards should be implemented nation-wide and a voluntary inspection system established to assure uniform compliance. Such standards should be referenced regarding controlling authority.

Recommendation #22: The MOU states that education/information programs for medical professionals is a key function of CBS. The hospital survey found that hospitals value the educational initiatives provided by CBS. It is recommended that the CBS develop strategies to enhance its role in educating stakeholders, particularly hospitals and physicians, on blood use and transfusion medicine. These strategies should include consideration of:

- Establishment of a portal or a designated portion of the CBS website for health care professionals
- Development of standard hospital and stakeholder educational packages for use by Centres; these packages would be prepared on a regular basis such as quarterly or semi-annually
- Requiring Centres to host a minimum number of educational sessions per year
- Developing performance measures related to education such as the number of educational sessions, the number of participants or organizations represented at educational sessions, evaluation results from educational sessions.Some provinces

(e.g. Ontario) have a number of educational initiatives in place in relation to the blood system and transfusion medicine. In addressing this recommendation, CBS should work with these provinces to minimize duplication of activity.

Recommendation #23: To ensure cost-effectiveness, donor recruitment should be monitored closely from the perspective of costs versus outcomes/benefits. Savings and other performance measures related to the establishment of the National Contact Centre should be tracked and reported.

Recommendation #24: A large component of blood collection costs is the cost of the blood bags equipped with special filters for leukoreduction. The bags costs approximately $42 each and CBS estimates a 5% wastage factor. It is recommended that a performance target be established to reduce the blood bag wastage factor. Given current collection volumes, just reducing the wastage factor by one percent (i.e. to 4%) would result in savings of about $340,000.

Recommendation #25: The professional fees and travel costs for the Change Control Initiative and the System Validation Project are substantial. CBS should provide the Members with detailed reports on the progress of these initiatives including the outcomes produced relative to the costs incurred.

Recommendation #26: The financial review revealed unexpected high expenditures in the areas of administration/overhead, travel and professional fees. It is recommended that Members and P/T Contacts closely monitor these cost items in CBS reports and if necessary, request a detailed audit of these costs before increased investment is made in these areas

Recommendation #27: It is recommended that CBS encourage research related to governance, management, administration and operation of a blood system in addition to the clinical/technical areas that are currently the focus of CBS' research and development activities. As noted earlier, this would support policy development by the Members and CBS.

Recommendation #28: The long-term role of CBS in R&D is an issue that should be discussed as part of the development of the CBS vision. The impact of various options should be assessed.

Recommendation #29: The existence of budget deficits at all Blood Centres except one is a concern that should be addressed. It is recommended that CBS re-examine the resourcing of the Centres relative to the overall budget approved by the Members to ensure that the core business is adequately resourced. CBS should assess the need for education and support for Centre Directors and staff in the areas of demand forecasting, budget development and budget management.

Recommendation #30: It is recommended that CBS develop and implement a cost recovery model for all Patient Services pending the outcome of the current project that will determine which Patient Services are to be maintained.

Recommendation #31: While there are some aspects of the Fractionated Products function that are outside of the control of CBS, it is recommended that CBS find innovative ways to manage fractionation cost increases. Consideration should be given to both strategies that increase supply in a cost-effective manner and strategies that reduce demand. For example:

- To increase the supply, CBS should make a decision about plasma self-sufficiency. The MOU identifies self-sufficiency in plasma collections as something that should be encouraged. The decision should me made in the context of a policy forum involving CBS, Members, Health Canada and the public. If plasma self-sufficiency is confirmed as a goal, various options for plasma self-sufficiency should be developed and analyzed from a cost-benefit-risk perspective.
- To reduce the demand, CBS should:
    - Develop national utilization guidelines for key blood components and products. This should be done in conjunction with the National Technical Working Group. Priority should be given to the development of guidelines for the use of fractionated products, particularly IVIG and Factor VIII because of their rapidly rising costs. Future consideration should be given to guidelines for high cost blood components such as platelets with a view to maximizing appropriate use and minimizing unnecessary discards. The Provincial/Territorial Ministers of Health will then need to decide whether to mandate the use of these guidelines in their health care systems as part of their provincial/territorial utilization management process. Ideally, these guidelines should be supported on a national basis
    - Disseminate the results of the IVIG Consensus Conference held in October 2000.
    - Explore a comprehensive range of utilization management options along a spectrum from guidelines to mandatory national standards to capping the fractionation budget for the provinces to charge back to hospitals (an option being explored by Hema-Quebec). The pros and cons of each option should be analyzed from a cost-benefit-risk perspective. For example, while capping the fractionation budget would limit costs, the risks would include public outcry from the hemophilia community and the possibility that hemophiliacs may not have access to the products they need once the budget cap is reached.

Recommendation #32: It is recommended that CBS identify ways to harvest the learnings from various provincial blood reference groups and hospital utilization committees that exist across the country. Specific suggestions might include an annual national forum (or series of regional forums) to share information from these various groups. The BC model for IVIG utilization management should be considered carefully for application to other provinces.

Recommendation #33: It is recommended that CBS consider using an expert advisory group, including physicians who use fractionated products and can provide information on clinical practice issues, to provide advice on the budget for fractionated products. The National Technical Working Group should also be considered a resource in this area.

Recommendation #34: In order to fully understand the implications of the use of Unrelated Bone Marrow Donor Registry (UBMDR), it is recommended that the current system of funding be re-evaluated as UBMDR has different cost drivers than Blood Operations. The full cost implications of the UBMDR program is not well understood, as the revenues generated from donor searches may not necessarily match the expenses incurred from completing those searches. Under the current system, all UBMDR expenses are accumulated and expensed as part of Blood Operations and all revenues received from donor searches are incorporated into the Blood Operations. As well, it is unclear whether or not all UBMDR search costs are fully accounted for, as there are additional overhead and administrative costs that may not be reflected in the fee schedule. If the UBMDR revenue and expenses were separated from the blood operations, there would be a greater degree of accountability for the costs associated with UBMDR. By separating UBMDR from blood operations, costs can be analyzed relative to donor search activities as opposed to blood collections activities. It is recognized that CBS is currently undergoing an audit of their UBMDR process and currently understands that more analysis must be completed to understand the full revenue and cost implications of this particular function.

Recommendation #35: There is a lot to be learned from exchanging information on financial and operational performance with other blood supply systems. It is recommended that CBS build on the international benchmarking process that was initiated for this review. The tool developed for this review provides an excellent starting point for ongoing benchmarking. It will be important to administer the survey with sufficient lead time for recipients to respond, taking account of seasonal issues.

Recommendation #36: CBS is facing a serious working capital situation as a result of large and growing volumes of fractionated product inventory. It is strongly recommended that CBS immediately cease the use of restricted funds to cover the working capital shortage.

Recommendation #37: CBS has identified a number of options for addressing the working capital situation and presented these to the P/T Contacts in June 2002. It is recommended that CBS move quickly to implement a strategy for alleviating the working capital issue. Based on the information that has been provided to the review team, we would suggest that the Members explore the option to finance the inventory as opposed to funding the value of the inventory upfront. However, the cost of financing and the ability of CBS/Members to provide some form of guarantee to a bank in order to access a line of credit must of course be important considerations. Discussions with financial institutions will be required to fully assess this option. Also, the lead Ministry should survey each province/territory about their preferred option and the capacity to contribute financially before proceeding. The recommended financing option should not be pursued in isolation. It should be combined with other strategies to address the growing costs of fractionated product including utilization management and vendor managed inventory models that were described previously in this report.

Recommendation #38: When communicating with P/T Contacts and Members, it is recommended that CBS link the working capital issue to the broader strategic policy context (i.e. it is more than an accounting problem, there is a need to manage product utilization).

Recommendation #39: Funding the fractionation product inventory is an immediate challenge for CBS. Currently fractionated products and other supplies (with some exceptions) are shipped from the suppliers to warehouse facilities in Ottawa and then shipped to the Centres. It is recommended that CBS assess the feasibility of a virtual warehouse (for supplies and fractionated products) with vendor managed inventory that is shipped from the vendor directly to the regional Centres. In the case of fractionated products, the main supplier (Bayer) currently collects plasma for fractionation from each Centre. The possibility for the same truck that collects the plasma to also deliver the fractionated products should be explored (storage requirements such as temperature –control will be a consideration).

Recommendation #40: It is recommended that CBS evaluate the opportunity to implement the SAP Inventory Management (IM) module across all inventories at CBS. The evaluation should consider the ability of the IM module to meet regulatory requirements for sign-offs.

Recommendation #41: The MOU makes very brief mention of the contingency fund but leaves the implementation of the fund open to interpretation. It is recommended that the CBS Board (via the Executive Management Team) draft a policy regarding the use of the contingency fund and submit it to the Corporate Members for approval. The draft policy should describe the history of the fund, the size of the fund, the purpose of the fund, the approvals process for use of the fund and how the fund is to be replenished. Accompanying background information should outline what the fund has been used for in the past, how much has been used, when it was used and whether Board approval was obtained for past use. The underlying assets (cash) related to this fund should be segregated and not used as part of general operations.

Recommendation #42: The budget process at CBS is extremely long. There is a tremendous amount of effort invested in the planning process that could be better spent on operations. It is recommended that the budget process be shortened to a maximum two to three months of active time. This will require the provision of provincial/territorial estimates on the amount of funding (or percent increase/decrease) likely to be available to CBS for the next fiscal year at a very early stage in the budget process.

Recommendation #43: It is recommended that the budget targets be established with the Members before the detailed budgeting is completed by the Centres.

Recommendation #44: The planning for salaries should be completed on SAP as soon as enough history is available in the system. This would eliminate the use of excel worksheets

Recommendation #45: It is recommended that the Corporate Members consider moving to an activity-based or volume-based budget model. The budget would become more focused on the volume of CBS outputs, rather than absolute dollars. Currently the funding formula for CBS is based on absolute dollars that are provided by the Members for a bundle of products and services. There is not a direct correlation of the dollars to the services that are budgeted or received. As the formula is structured today, if the volume of Red Blood Cells required by the provinces and territories increases, CBS must increase their collections, testing and distribution, without any additional funding. Also, if Members feel that the budget requested by CBS is too high, a budget reduction is communicated in terms of a dollar or percentage decrease in overall funding not in terms of an agreed upon reduced level of product or service.

Some of the benefits of an activity-based budgeting approach are:

- Links the planning process to the key performance measures
- Relates costs to activity versus an absolute cost factor
- Identifies the key drivers of cost of operations
- Enables the identification of manageable cost elements versus cost elements which are out of the control of the organization
- Promotes greater awareness of how costs relate to activities
- Can form the basis of a "contract" between the Members and CBS for CBS to provide a certain volume of product

A formula could be developed that is structured with fixed and variable cost components. The Members could review the fixed cost components and agree to a reasonable change, then agree to what would be included in the variable components. Members' expectations for operational efficiencies would be incorporated in to the development of the variable (i.e. unit cost) component. For example, in Blood Operations, performance targets could be set for areas like donor recruitment or finance. Pure variable costs such as blood bags and test kits would be planned for based on the volume of collections. The budget prepared for the Members would include the fixed costs spread across an agreed upon volume plus a variable cost component per unit of volume.

At a minimum, this approach should be considered for Fractionated Products, which are largely demand-driven, and possibly for blood operations. If activity-based budgeting is adopted for Blood Operations it will be important to identify performance measures that will be monitored regularly to ensure that incentives remain for maximizing cost-efficiencies. The current budget process for Patient Services and UBMDR should be maintained. The funding formula should be agreed to by the Members before the budget process begins. During the budget process CBS could populate the formula with the actual dollars, which would be presented to the Members for approval. This shift in budgeting approach would not change the Member budget approvals process. The approvals process should continue as it is and CBS would be required to return for Members approval of significant increases.

Recommendation #46: Currently, CBS is unable to report an accurate cost for each of the blood products it produces and the services it provides. It is recommended that CBS develop appropriate costing models to identify the unit cost of each of its products and services. This includes:

- development of unit costs for plasma and platelets (consideration should be given to contacting US blood centers that routinely produce price lists of specific blood products)
- re-evaluating plasma centre costs and distributing them to the cost of Fractionated Products; full costing should be performed to capture all direct and indirect costs of maintaining plasma collection operations.
- re-examination of the formula used for determining the cost per unit of red blood cells; the current formula produces a misleading result and also makes benchmarking with other blood service agencies very difficult. CBS currently reports this cost per unit with the inclusion of items such as UBMDR, research and development and plasma centres. CBS should calculate this performance measure without these extraneous cost items.

For example, by only including the following costs:

Re-evaluation of Total Blood Operation Cost per Unit of Whole Blood Collected	**2002**	**2001**
Donor Recruitment	27,353,449	23,487,435
Blood Collections - Whole Blood	94,227,625	85,367,737
Manufacturing/Processing	10,850,991	9,230,203
Donor Blood Testing	42,793,563	40,100,201
Storage and Distribution	17,623,757	16,396,643
Quality Assurance and Quality Control	16,483,949	10,206,137
Administration/Overhead - National Level	45,183,392	39,527,203
Administration/Overhead - All Regional Blood Centres	40,231,729	39,271,727
Other	23,739,693	14,971,666
Sum of Total of Re-evaluated Blood Operation Costs	**318,488,148**	**278,558,952**
Whole Blood Collections	**803,625**	**740,909**
Total Re-evaluated Blood Operation Cost per Unit of Whole Blood Collected	**396.31**	**375.97**

This is only a starting point and these costs would have to be re-evaluated even further because the costs contained in the Administration/Overhead also include resources associated with Patient Services, UBMDR and Fractionated Product overhead costs. An exercise may be required to fully break apart these costs using a form of activity-based costing in order to truly predict an accurate cost of blood operations.

Recommendation #47: Corporate Members are concerned that the information provided does not always meet their needs. CBS should maintain a close working relationship with the P/T Contacts, Lead Ministry and others that can help them proactively identify the information needs of the Corporate Members.

Recommendation #48: CBS should ensure that all budget submissions are developed in accordance with Member requirements. It is critical that Members needs are met, even if additional information/options are included as well. The budget submission and corporate plan must highlight the application of a cost/benefit/risk framework to support requests for new programs and initiatives.

Recommendation #49: Building on the "Checklist for Consideration In Ongoing Budget/Business Planning Processes" (June 2001) the Corporate Members (via the P/T Contacts) should develop a template for the CBS budget and corporate plan. (a sample is attached in **Appendix G**)

Recommendation #50: The template included in Appendix G includes a table for the reporting of budget information by functional area (e.g. donor recruitment, collections, testing, etc.). CBS does not currently report data to the Members in this fashion so it will be difficult to provide comparative historical data on this basis. However, expenditures by functional area will provide Members with a better sense of what funds will be used for. It is therefore recommended that the reporting of expenditures by functional area be piloted for the next budget cycle, in addition to the current budget format. Members should assess usefulness of the information provided and advise CBS on the most effective format to use going forward.

Recommendation #51: CBS should continue its plan to split fractionated products into a separate set of books to ensure that the costs are kept separate from those of blood operations. It is also recommended that CBS further split their reporting of blood operations into the main business activities: Blood Operations, Patient Services and UBMDR. There are different cost drivers for each of these business areas, therefore it would be important to report them separately so that the performance of each area could be monitored and managed. This does not eliminate the need to also present a consolidated budget that provides the Corporate Members with information on the total overall budget figures.

Recommendation #52: CBS should consider using a rolling 12 month forecast approach. The 12 month rolling forecast would mean that there would always be a budget or forecast for 12 months out at any time. As each month passes, another month is budgeted at the end of the cycle. (A rolling forecast approach is currently in place for Fractionated Products.) The benefits of using a rolling forecast approach are:

- A more externally focused, market sensitive process
- A more direct linkage of the organization's strategic plan to top-level plans through the lowest level departmental detail
- More forward-looking, decision making data
- A more streamlined process with lower resource requirements; and
- An increased accountability within operating units, driving business action, not rationalization

If rolling forecasts are not prepared, then quarterly forecasts should be prepared within the fiscal year to update the plan with any known changes.

Recommendation #53: CBS should re-evaluate their financial staff requirements at both the regional centres and at the head office to eliminate duplicate functions. There are a significant number of finance staff at both the regional Centres and at the head office that are performing functions such as preparing financial reports and conducting budget forecasts.

Recommendation #54: There are approximately 12 staff working in Accounts Payable which seems high given that close to half of the organization's expenditures are to one or two major suppliers for fractionation and there is only one supplier of blood bags. It is recommended that CBS conduct an assessment of the resourcing of the Accounts Payable function and alternative approaches to providing this function.

Recommendation #55: In addition to initiatives already identified by CBS, there are other opportunities to improve efficiencies in the financial function that should be explored. Based on the experience of other organizations where a top tier ERP system is in place like SAP, there is the potential to save in the range of 25% in purchasing and accounts payable by simplifying and standardizing the processes and moving to shared services. High value practices would also need to be implemented to fully realize the potential benefits available. For example, in the purchasing and accounts payable area to realize savings the following changes to the process could be implemented:

- Negotiate national contracts for commonly purchased items
- Set up catalogues for common repeated purchases; all purchases for these items would be purchased via catalogue
- Use purchase orders for all purchases
- Two way matches (purchase order to receipt) are set up for payments, eliminating the receipt and processing of the invoice
- Payments are made via electronic funds transfer and cheque payments are discouraged.

By negotiating national contracts and ensuring that all purchases for items on the catalogues are purchased via the catalogues there is also an opportunity to realize savings on the purchase price. There will be an opportunity to negotiate better pricing given the improved negotiating position CBS would be in by leveraging the national purchasing volume. It is important to note that in the case of CBS the savings potential relates mainly to non-medical supply costs.

Recommendation #56: One of the findings from the review is that some key products have a single supplier. There are advantages and disadvantages to having a single supplier. The advantage is usually access to volume discounts. A disadvantage or risk is the total reliance on one supplier in the event that the suppliers operations are discontinued either temporarily or permanently. While some organizations have chosen to adopt a policy around always using multiple suppliers there is value in addressing this issue on a case by case basis that would consider all of the relevant facts. For example, the balance of costs such as extra SOPs and training if there are multiple suppliers with slightly different products vs risks (contingency plans) vs benefits. It is recommended that CBS conduct an assessment of the costs, benefits and risks of single vs multiple supplier arrangements for key items including blood bags. This approach should also be taken for high volume, high cost fractionated products that also tend to be purchased from one or two suppliers. CBS should continue to use a rigorous RFP process to obtain competitive prices on single source products.

Recommendation #57: CBS was able to standardize the financial processes across the organization when SAP was implemented, but they should now go back and identify additional benefit opportunities. They have a very good tool in place, but there is a need to review the processes to ensure that they realize the benefit of having such a tool.

Recommendation #58: It is recommended that CBS consider the implementation of employee time-entry as a next-stage project for SAP. The examination of the benefits associated with the elimination of manual time-entry should be included in the proposed post-implementation review of the HR-Payroll system. The savings associated with the elimination of the paper-based time capture system should be part of the business case validation that precedes this project.

Recommendation #59: It is recommended that CBS prepare reports that place more emphasis on summarizing the issues and actions, rather than providing accounting detail. CBS generates many different reports, such as the monthly Management Reports, that offer a large amount of detail and insight in the operations of CBS. This does not however give a good overview of the operations quickly and would require a significant amount of time to understand the report. Therefore, CBS should consider creating a "dashboard" that highlights only the key performance indicators for the user and the major factors affecting its costs.

Recommendation #60: CBS also needs to pay close attention to their audience when preparing reports. This is especially important for the Members where there may be turnover in the positions and the new person in the role may have a different understanding and expectations from the CBS. It is recommended that both the internal and external users of the financial information be surveyed on a regular basis to ensure that they are receiving the information required to perform their role (this can be done on a formal or informal basis).

Recommendation #61: It is recommended that CBS establish performance measures to assess the performance of the financial function. Possible measures for consideration include:

- Purchasing/Accounts Payable
    - Percentage of payments that are non-purchase order related
    - Number of invoices processed per Full-Time Equivalent (FTE)
    - Number of active vendors
    - Number of blanket purchase orders
    - Percentage of payments made via Electronic Funds Transfer (versus cheque)
- Billing/Accounts Receivable
    - Number of invoices processed per FTE
    - Percentage of invoices that are error free
    - Days Sales Outstanding (DSO)
    - Percentage of Bad Debts
- Time Capture
    - Number of time reports processed per FTE
    - Ratio of Time Capture employees to Total employees
- Overall Finance
    - Cost of the Finance function as a % of total expenses (done as a % of Total Revenue in most orgs)
    - Number of days from the close of the month to the creation of management reports

- Total number of days to prepare the annual budget

Recommendation #62: With the potential implementation of large projects such as the national contact centre and the Client Relationship Management application, it is recommended that CBS consider the creation of a central project management office (PMO). The PMO should employ an accepted set of project management practices and tools to centrally manage the multiple issues and dependencies the proposed initiatives are expected to create.

Recommendation #63: The PMO described above should be charged with coordinating the implementation of the IS recommendations contained in this report.

Recommendation #64: As part of any new IT initiatives or the creation of a project office, it is recommended that CBS review its change management and training planning. Initial implementation and refresher training for applications should be managed centrally by IS.

Recommendation #65: As part of its PC and laptop renewal, it is recommended that CBS review its PC platform purchasing options so that it is not purchasing all its PC assets at once. CBS should consider staggering its capital purchases based on accepted hardware lifecycles (e.g. renewing one third of its desktop PCs each year assuming a three year lifecycle) or leasing with its current hardware vendor. Either approach would allow CBS to better manage the capital implications of hardware purchasing and integrate into the annual planning process. Any negotiated contract should include hardware platform version freezing so that CBS has similar machine platforms if it decides to purchase machines across a drawn-out timeframe.

Recommendation #66: It is recommended that CBS consider the implementation of an internal chargeback or cost allocation mechanism for telecom and office equipment costs. The current inability of IS to hold other business units accountable for costs or to influence behaviour may lead to ongoing increases of this budgetary component.

Recommendation #67: The current division of administration and operations management within IS could potentially lead to functional overlaps should SAP be selected for Client Relationship Management or if the current data warehouse functionality begins to impact on administrative systems. It is recommended that CBS review the organizational impacts and synergies of these two groups and consider re-aligning responsibilities.

Recommendation #68: It is recommended that CBS continue to review its disaster response capability and consider the adoption of an accepted framework such as ITIL Service Management for evaluating its availability and continuity requirements. The adoption of any mitigation measures for enhancing availability or expanding continuity measures should be included as part of the IS portfolio planning process.

Recommendation #69: The current burden of five and seven part regulatory approvals for all changes to the BLIS system is burdensome. It is recommended that CBS and Health Canada explore the creation of pre-approved procedure for break, fix and maintenance procedures.

Recommendation #70: The current time-lag in getting clinic results (total donors) from the BLIS system makes strategic planning of additional clinics difficult. The integration between the systems should be strengthened and possibly could be bridged via the current Cognos data warehouse without requiring external experts or additional applications.

Recommendation #71: It is recommended that CBS consider eliminating the PDSI system and include the donor scheduling and call list generation capabilities into the ESS system until the Central Contact Centre and CRM initiatives are complete. This project could use in-house development expertise, while the savings from discontinuing PDSI would come from the cancellation of license and support costs.

Recommendation #72: The use of the CPM model used in planning clinic resources in ESS does not reflect actual clinic capability. In densely scheduled clinics, donors often have to wait too long for service and leave frustrated. It is recommended that the resource scheduling model be revised to reflect actual clinic capability.

Recommendation #73: The remote capabilities of PDSI are limited and often result in database issues such as faulty entries if a replica of the database is re-synchronized with the network version. It is recommended that CBS explore the use of mobile technologies or the expansion of remote access capabilities as part of the replacement of PDSI to allow for field staff to have updated schedules and donor information. It is expected that a limited pilot of a packet based mobility solution could be tested for less than $10,000 (wireless card and usage metering) if there are no major software revisions required to access the application remotely.

Recommendation #74: The current ESS/PDSI does not allow CBS to strategically telemarket to donors outside of clinics they have frequented in the past. As part of any new functionality, it is recommended that CBS explore a decision support system that would allow telemarketers to solicit potential donors if a clinic is closer to their home than one they have used in the past. This functionality would ideally be integrated into the successful CRM application that CBS selects. This capability might allow additional strategic capability such as directing donors to clinics that are not historically operating at capacity.

Recommendation #75: It is recommended that CBS review its SAP licensing agreement and continue to benchmark their per seat costs against other Ottawa companies and government organizations. CBS should continue to explore aggressive enterprise re-pricing contracts that allow for tiering of user types as additional modules are considered. Should additional modules be identified for implementation, CBS should consider completely re-negotiating its licensing and review potential structures such as enterprise pricing (e.g. my SAP enterprise licensing). CBS through discussions with the Treasury Board has begun re-negotiating SAP seat costs and should be able to half what it currently pays per seat. Should the use of SAP be expanded such as what would occur with on-line time reporting, an enterprise or tiered license could save $1,000 to $2,500 per user from the current licensing costs.

Recommendation #76: It is recommended that CBS complete the "Strategy Map" in a timely manner by identifying performance measures and targets for all of the objectives identified. For example, there are currently no measures in place to address the goals of awareness of blood and blood products, establishment and maintenance of positive and productive relationships or the establishment of the CBS as a Centre of Excellence in Research and Development.

Recommendation #77: It is recommended that CBS consider including the following additional performance measure in its Strategy Map and/or operational performance measures:

- The hospital-based indicators of adequacy and efficiency such as elective surgery cancellations, platelet reductions, hospital discard rates, etc.
- Overhead costs per unit, or overhead costs as a percentage of total costs.
- Indicators related to fractionated products (e.g. outdate rates, issue to order ratios)
- Indicators to measure the performance of the finance function (see financial review section)
- Indicators related to educational sessions held by CBS (local and national)
- Number of research papers published or conference presentations
- Improvement in relations with external stakeholder groups (this could be measured through a survey by an independent group)

Recommendation #78: It is recommended that CBS re-visit the targets that have been established for some of the key performance measures with a view to "raising the bar" for these measures. Examples include:

- The target for meeting hospital demand should be to meet 100% of hospital demand every month (rather than the current target of 95% of hospital demand nine out of 12 months of the year)
- The target discard rates for whole blood, red blood cells and platelets should be re-examined based on international benchmarks

Recommendation #79: It is recommended that CBS establish targets for each Centre for costs by activity level. Current operational performance measures are not specific to Centres. For example, there is an overall target to reduce the cost per unit of red blood cells by 5% regardless of how the Centre is currently performing.

Recommendation #80: The wording of the current donor screening form is rather advanced, particularly for people whose first language is not English. The ability of donors to clearly understand the questions on the form and give an informed consent is critical from a risk management perspective. It is recommended that CBS review the current donor screening form with a view to simplifying the wording. The review should include an assessment by a "plain language" specialist as well as input from donors and the public.

Recommendation #81: It is recommended that CBS explore innovative methods of donor screening that are less reliant on the literacy level and language capacity of donors. For example, consideration could be given to the use of interactive video technology which is in place at some blood centres in the U.S.

Recommendation #82: CBS is currently using NAT testing for HCV and HIV on an investigational basis. NAT-HCV has been used for approximately three years. Given the high cost of the tests, the very small number of window cases and the fact that other countries that introduced NAT are reconsidering it use, it is recommended that CBS conduct a re-evaluation of NAT testing including a thorough cost-benefit-risk assessment based on evidence that has been gathered during the investigational stage (e.g. total cost expenditures, total number of confirmed window cases, other benefits) and on international experiences.

Recommendation #83: Hospitals and physicians are CBS' customers and the only links to the recipients of blood components and products. Currently, CBS' mandate ends at the hospital door and so does its access to knowledge. It is recommended that CBS shift its knowledge boundary in order to increase its knowledge of what happens to blood components and products after they are received by hospitals. The following specific strategies should be considered:

- Developing a list of hospital-based performance indicators that would allow CBS to assess the adequacy of the blood supply system. These measures should include:
    - the number of elective surgery cancellations due to blood shortages
    - the number of platelet reductions due to blood shortages
    - the number of blood transfusions
    - the number of adverse reactions to blood products
    - the discard rate for specific blood components and blood products (both indate and outdate)
    - the volume and type of blood components and blood products shipped to, or received from, other hospitals
    - inventory levels in the hospitals
- Developing electronic linkages between the proposed MAK system and the hospitals that would permit true "vein to vein" tracking of products and information. There are cost implications to this recommendation that would need to be identified and considered in light of benefits, risks and the resources available to the Members.

Recommendation #84: The plasma centres are located in relatively small communities. Development of a plan for plasma self-sufficiency should include an assessment of the most cost-effective locations for plasma centres.

Recommendation #85: Total labour hours per collection at CBS is much higher than in the countries that participated in the international benchmarking survey. It is recommended that CBS continue to benchmark this indicator with other systems and identify reasons for the variance and opportunities for efficiencies based on practices in other jurisdictions.

Recommendation #86: It is recommended that CBS conduct assessments of the costs, benefits and risks of various collection centres, clinic models and alternative collection processes; (e.g. Bloodmobile) in order to focus future investment on the most cost-effective collection methods.

Recommendation #87: Discard rates are above desired levels both at Regional Centres and at hospitals (although data is limited). Based on the results of the hospital survey, the value of discarded blood components is at least $6 million and perhaps as high as $16 million. It is recommended that CBS develop strategies for Centres to use to minimize discard rates of all blood components and products. Even a 10% reduction in discards could result in savings of up to $1.6 million. Strategies should consider the work already being done in provinces such as British Columbia.

Recommendation #88: It is recommended that CBS re-evaluate their role in facilitating effective inventory management of blood and blood products throughout the blood system (including hospitals). Examples of strategies that might be considered include:

- Revisiting the policy of not accepting blood or blood products once they have been delivered to hospitals; consideration might be given to developing a formal agreement (e.g. Memorandum of Understanding or Service Level Agreement between CBS and hospitals) that would the set out the criteria under which CBS would accept indated returned products from hospitals. Criteria would address such parameters as proper storage, temperature control and transport requirements. The Australian Red Cross Blood Service is moving in this direction.
- Playing a coordinating or brokerage role in the exchange of blood components and products among hospitals. Some hospitals across the country have arrangements with other hospitals for the exchange of blood components and products to minimize discards due to outdating. Some of these arrangements are more formal than others. Given the importance of being able to accurately track the ultimate destination/recipient of blood components and products (for lookback/traceback purposes), it would be helpful for CBS to provide coordination and guidelines for the exchange of blood units among hospitals.

Recommendation #89: The results of the last Census show that Canada's ethnocultural population is growing and the nation is becoming more diverse in terms of culture and language. Given the need for CBS to increase its donor base to keep pace with growing demand, it is recommended that CBS identify ways to enhance responsiveness to Canada's growing multicultural community. Strategies considered should include:

- Allowing for translation and interpretation support in the donor screening process
- Multi-lingual advertising in the ethnocultural media
- Multi-lingual educational materials about blood donation
- Targeted recruitment of volunteers from ethnocultural communities
- Holding clinics in communities with high ethnocultural populations
- Establishing a multicultural advisory committee to advise CBS on the most effective ways to increase donations from multicultural communities
- Promoting the innovative practices that some of the Centres have adopted (e.g. one Centre organized clinics for the Muslim community with separate donation times for men and women or curtains to separate the male donors from the female donors).

Recommendation #90: Hospital survey respondents provided a number of suggestions for improvement of customer service and efficiency. The most common area identified for improvement was transport services. Since this review did not permit a detailed examination of specific hospital concerns, it is recommended that CBS conduct an investigation into hospital satisfaction levels and issues in relation to transport services.

Recommendation #91: The hospital survey found that a high proportion of hospitals have never been consulted by CBS (local or national) about the level of customer service they receive. It is recommended that CBS develop and implement a National Customer Service Strategy. The strategy should include ongoing mechanisms to measure hospital satisfaction levels with the various services that CBS provides. The strategy should also identify the core basket of services that CBS offers hospitals at both the local level and national level, for example free routine deliveries of required blood components and fractionated products, educational sessions, regular meetings, bulletins, newsletters and information lines. Consideration should be given to administering a regular hospital survey similar to the one conducted for this review.

Recommendation #92: There is some concern with the manner in which the function of the Chief Risk Officer is currently divided between the General Counsel and the Executive Vice-President Safety and Performance Management. As a general practice, a single point of management is the clearest approach to ensure delivery. An additional level of due diligence is introduced in many organizations through a cross-functional risk oversight committee of peers (usually comprised of CEO direct reports). The risk oversight committee is charged with reviewing and signing-off on all risk management related matters before they are tabled with the CEO. Thereby, bringing to bear a multi-discipline, cross-functional, corporate forum for vetting of all proposals in relation to their risk profile. It is recommended that CBS make the establishment of this type of risk management committee an organizational priority to that it is introduced in a timely manner.

Recommendation #93: It is recommended that Board policies be reviewed to ensure congruence with risk management. Several policies can be seen as touching upon risk. Once clarity is provided regarding the relative status of risk, these policies should be rationalized accordingly. In particular, the Risk Assessment Policy could be broadened into a Risk Management Policy. If the wording could be modified to ensure that the 'reasonable standard of care' described encompasses good risk management practices. And the apparent bar could be raised to make it the goal to exceed the regulations, rather than to comply with them.

Recommendation #94: Should agreement on clarification of the MOU (see recommendation #1) prove to be practically impossible, it is recommended that the CBS Board directly deal with the conflict. The Risk Management Framework should be amended to specifically note the apparent differences in the principles stated in the MOU. The Framework should address these differences, and resolve them if possible. This might be accomplished by interpreting the wording in such a way as to equate them, or by distinguishing situations where one approach or the other is preferred. Ultimately it may be necessary to choose one over the other, however this should only be done after a thorough legal analysis of the MOU to determine which approach should override the other. In the absence of an agreed upon national level of risk tolerance, this process should also help the Board to articulate its own level of risk tolerance for the organization.

Recommendation #95: Sending a common message for risk management is important, particularly in an implementation. A common approach should apply, so that all risk management activities have a universal 'feel' to them. Tools used for risk management should tend to reflect the approach in the framework. This reduces the potential for confusion over risk management, ensuring that people know what tools they are using, and why. It is recommended that CBS design the Risk Management Framework as a common template from which to derive others. CBS should try to make all other risk management frameworks within the organization 'look and feel' similar. Certainly risk management tools must be tuned to suit the specific needs of particular functions or processes. However, this is best accomplished by adding additional information to a common template wherever possible. When it is seen as preferable to deviate from the common template (e.g. to simplify the table), ensure that such deviation makes practical sense, is approved by the Risk Management Director, and specifically note that this is a deviation in the functional framework itself. Specifically include a reference to the CBS Framework in the tool (perhaps by footnote). Since the CBS Framework is still undergoing revision, it could be expanded or modified to be consistent with some of the processes and tools used elsewhere in the organization. Another approach would be to revisit the tools themselves, by specifically mapping various steps in the tools to the Risk Management Framework. This could ensure consistency of application, since those using the tool can better understand which step in risk management the tool is designed to support.

Recommendation #96: It is recommended that a common risk management language be developed by CBS. CBS should determine where terminology and language is incongruent, and resolve these. This should apply to terms within different risk management tools, and also to terms commonly used that have different meanings or connotations within the organization. CBS should add a glossary of terms and concepts to the framework and standardize risk management tools along with the framework, displaying a 'common front'. CBS should communicate early and often, using the terms consistently.

Recommendation #97: To fully integrate risk management into decision-making, it is recommended that CBS apply the framework to the decision making process as it progresses. CBS should break the Framework out into its individual Steps, and ensure that each step is individually documented at the corresponding step in the decision process. Step 1 can be documented early on in the process, since that is where it naturally fits. Other steps can be applied and documented at their appropriate stages. As each step proceeds, CBS should be sure to review previous stages, and repeat them if necessary, since each step can provide new information that may not have been considered for a previous step. CBS should document these updates as required.

Recommendation #98: It is recommended that CBS use the framework (or appropriate tools) like a template, methodically applying risk management steps and processes. Only skip over particular steps when there is good reason to do so. The tools should be applied by default, and exceptions should be justifiable. As a specific example, the frequency/magnitude grids should be used wherever possible, and the results documented. There are two main reasons for the need for discipline here. Actually completing these tools ensures that the full process is carried out. It reduces the chances that an important factor could be misjudged or overlooked in haste. And the results can sometimes be surprising, which will raise new issues, or new questions concerning the accuracy of the assessment.

Secondly, discipline is important in the earliest stages of risk management implementation. Use of the tools models that behaviour for others. It shows that this is part of the job, and will encourage others to follow the process. It makes it more likely that risk management will catch on in CBS, and will not be seen as a 'passing fad' imposed by management.

Recommendation #99: To complete an organization's understanding of risks, it is recommended practice that each of the organization's exposures/risks be subjected to "stress-testing". Worse case scenario analytics allow an organization to assess its preparedness, identify the effects of a risk event, risk correlations and respond accordingly through appropriate amendments to the risk management infrastructure. "Stress-testing" can be viewed as a "fire drill" designed to assess the robustness of the existing risk management infrastructure to existing or hypothetical risks. In effect, fire drills are meant to ask all the difficult questions – ahead of an event. It is recommended that CBS incorporate this approach into its risk management process.

Recommendation #100: It is recommended that CBS send the message that risk management is the future, from the top. CBS should ensure that all managers model the correct behaviour, by visibly using the framework, models and tools.

Recommendation #101: There are a number of initiatives underway and CBS must ensure that risk management receives appropriate attention. Risk Management must be integrated, coordinated and communicated along with the other changes. It is recommended that CBS obtain change management support, either internally or externally and ensure that change management resources are dedicated to risk management.

Recommendation #102: It is recommended that CBS survey the staff on their understanding and readiness for risk management. Seek their input on plans, and involve them wherever possible. Standardize the approach across Centres, but ensure that each Centre is getting the same message by monitoring and following up on feedback.

Recommendation #103: It is recommended that CBS integrate the approach to risk management with other activities and training. CBS should ensure that risk management is seen as part of the job. There is a need to stress discipline in the risk management process and show staff that documenting is for their benefit as well. CBS should seek a balance between education and audit. Audits should be a vehicle for learning, rather than a technique for punishment.

Recommendation #104: It is recommended that CBS ensure that ongoing review of the risk management framework is carried out. The following suggested Risk Management Best Practices provide guidance for ongoing review of the risk management framework:

- Get top management and Board buy-in
- Recognize and understand the politics of the organization
- Involve similar groups in risk management planning
- Involve frontline staff and volunteers

- Balance compliance and risk management
- Make risk management a Senior-level management responsibility
- Create awareness
- Promote a philosophy that education is better than punishment
- Establish a common risk management language

8. Conclusions

CBS has come along way in its short, four-year history. Many board members and staff commented that the situation they inherited was worse than they thought. There were lots of bridges to build and fences to mend but more importantly there was a great deal of work for the new leaders to do. What did not take long however, was the process for the leadership to understand the mandate of the organization and to embrace the concept of "safety is paramount" that has come to characterize CBS in the eyes of many stakeholders.

This review found an organization in which board members and executive leaders are committed to the success of the organization. Although the review did not include many opportunities for contact with frontline workers, when board and management were asked to identify the strengths of the organization, the frontline staff was the most common response. Clearly, CBS is evolving and will soon be "transforming" as it attempts to keep pace with international best practices in blood operations.

CBS' ability to achieve its Transformation objectives and to continue to satisfy the terms set out in the Memorandum of Understanding will depend on its ability to address a number of issues that have been discussed in detail in this report including:

- Achieving a quick and effective resolution to the working capital issue in relation to growth in the value of inventory; it is critical that restricted funds not be used for purposes other than those for which they are intended
- Contributing to and showing leadership in the development of utilization guidelines and strategies, particularly for fractionated products
- Convening policy forums in collaboration with key stakeholders to address important national issues such as plasma self-sufficiency
- Ensuring that decision-making is, *and is seen to be*, evidence-based and consistent with the cost-benefit-risk framework described in the Memorandum of Understanding
- Developing a rigorous program management approach and change management strategy to guide the Transformation process
- Enhancing the focus on hospital customers through a national customer service strategy that shifts the knowledge boundary beyond the hospital door to gather meaningful information on the adequacy of the blood supply and customer satisfaction
- Developing formulae to determine the unit costs of the various products and services provided
- Achieving operational efficiencies by identifying strategies to minimize discard rates, improve inventory management, etc

- Improving standardization across Centres in keeping with the vision of a truly national, centrally regulated blood system
- Continually improving upon the corporate and operational performance indicators that have been introduced and setting aggressive targets
- Ensuring that Blood Centres are adequately resourced and soundly managed within fiscal parameters

Although the focus of this review was CBS, there were a number of opportunities for improvement identified that require collaboration between CBS and its Corporate Members. First amongst these is the need to continue to strengthen the relationship and improve communications between CBS and the Members. Second, there is a need for clarity of vision, roles and policy direction that will only be possible through joint planning. This should entail a review of the MOU to address ambiguities that threaten to hamper decision-making. Third, the challenge of how best to balance safety and affordability is ever present. In a climate of scarce health care resources, it will be critical for the Members to identify, with input from CBS, a policy framework that will allow the "tough decisions" to be made. Fourth, rising demand and rising costs of blood products requires effective utilization management that can only come from those that have the authority to oversee provincial health care resources. There is an urgent need for clear, effective utilization guidelines and strategies to encourage compliance.

In the coming months, it will be important for the Members and CBS to develop implementation plans for moving forward with the recommendations emanating from this review.

Appendix A

Federal / Provincial / Territorial Information & Documentation

1.	Hill, Julia, A/Director General – Health Canada: Questionnaire response (written)	July 11, 2002
2.	Good Manufacturing Practice Guidelines – 2002 Edition	2002
3.	www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate	
4.	Health Canada - Therapeutics Products Programme: Guidelines Good Manufacturing Practices	1998
5.	Health Canada - Drugs Directorate Guidelines: Blood Collection & Blood Component Manufacturing	1992
6.	Health Canada - Therapeutics Products Programme: Annex to the Good Manufacturing Practices for Schedule D Drugs Part 2: Human Blood and Blood Components	December 1, 1999
7.	Health Canada - Therapeutics Products Programme: Expert Advisory Committee on Blood Regulation – Public Meeting Minutes	1999 - 2001
8.	Health Canada: Towards a Renewed Regulatory Framework for the Safety of Blood and Blood Components intended for Transfusion	
9.	Health Canada: Safety Standards for Blood and Blood Components	
10.	Health Canada: Canadian Standards Association Standards Development Process	
11.	Health Canada: How Health Canada develops Policies and Regulations	
12.	Health Canada: Health Canada – Our Role	
13.	Corporate Members Minutes	August 1998 – November 1999
14.	Federal / Provincial / Territorial Memorandum of Understanding	1996
15.	Canadian Blood Services: Corporate Business Plan 2001/2004 and Budget Information: Provincial / Territorial Liaison Committee Request for Supplementary Information	November 19, 2001
16.	Common Provincial / Territorial Canadian Blood Services (CBS) Annual Budget (2002/03) Briefing Note	November 19, 2001
17	Provincial / Territorial Canadian Blood Services (CBS) Annual Meeting-Supplementary Fractionated Increase	September 17, 2001

	Options. Common Briefing Note	
18.	Questions from Provincial / Territorial Representatives Related to 2002-2003 Budget	September 1, 2001
19.	Checklist for Consideration in Ongoing Business Planning Processes	June 29, 2001
20.	Common Provincial / Territorial Consensus Process	February 1, 2000
21.	The Commission of Inquiry on the Blood System in Canada (Krever Commission)	1997

Canadian Blood Services General Documentation

22.	KMI Benchmark Performance Review	
23.	Building a Foundation for the Future: Organizational Model and Delivery Systems Project – Phase 1 Summary	July, 1999
24.	Canadian Blood Services Public Participation Task Force: CBS, the Blood System and Public Participation: An Overview	April 14, 2000
25.	Canadian Blood Services: A Report to Canadians. Our First Six Months	September 15, 1999
26.	Canadian Blood Services: A Report to Canadians. 1999/2000	October 4, 2000
27.	Canadian Blood Services: A Report to Canadians. 2000/2001	September 24, 2001
28.	Canadian Blood Services: Record of Donation	July 27, 2001
29.	Canadian Blood Services Corporate Strategy - 2002-2006: Provincial / Territorial Contacts Meeting	June, 2002
30.	Canadian Blood Services Hospital Customer Service Coordinator – The BC & Yukon Experience: Position Review and Recommendations	April, 2002
31.	Canadian Blood Services: National Fact Sheet	January 16, 2002
32.	Letter to W. Rees: List of Document Types	January 27, 1999
33.	Canadian Blood Services: Document Definitions	July 18, 2002
34.	Canadian Blood Services: SOP Business Process Flow Map. v15	March, 4, 2002
35.	Canadian Blood Services: Operating Procedure SPM.0001: Change Control (Working Copy)	March 3, 2002
36.	Canadian Blood Services: SOP 01 101 - Phlebotomy	May 26, 2000

	(Whole Blood) - Working Copy	
37.	Canadian Blood Services: SOP 01 101 – Phlebotomy (Whole Blood) Lesson Plan	November 25, 2000
38.	A variety of Canadian Blood Services Staff and Public Newsletters	Multiple dates
39.	Canadian Blood Services: Freedom Of Information Policy	
40.	Binder labelled "Miscellaneous"	
	• Blood Donations Exceeded Needs/Products from 4, 000 Donors after Terrorist Attacks Must be Discarded	
41.	• NAT/PCR Testing	
42.	• Leukoreduction of the Blood Supply	
43.	• Captive Insurance	
44.	• Stored Blood Samples	
45.	• Deferral of UK Travelers	
46.	• Canadian Blood Services Survey - CBS Web Survey of Donors	
47.	• Canadian Blood Services Survey - Winter 2002 General Public Research Program – Final Report	Winter 2002

Canadian Blood Services Organizational / Performance Information & Documentation

48.	www.bloodservices.ca	
49.	Canadian Blood Services Strategy Map - Draft	March 3, 2002
50.	Clinic Performance Monitoring Year End Report 2001 / 2002	April 26, 2002
51.	Interim Performance Measures Report – April 2002	April 2002
52.	Operations Divisional Performance Measures April 2002	April 2002
53.	Guide to Operations Divisional Performance Measures	
54.	Performance Management Program	2002
55.	Canadian Blood Services: One Bed Clinic Model	May 6, 2002
56.	Canadian Blood Services: Monthly Management Report	
57.	Canadian Blood Services: Scope of Services Project	June, 2002

58.	List of Current Patient Services	2002
59.	Appendix I: Variation within Areas of Donor Testing	
60.	Appendix II: Variation of Blood Product Availability	
61.	Appendix III: Special Services Offered by some Centres	
62.	Appendix IV: Patient Services: Testing	
63.	Appendix V: Scope of Prenatal Services	
64.	Canadian Blood Services Corporate Strategy 2002 - 2006	April 16 - 17
65.	International Benchmarking: Presented to Provincial / Territorial Contacts	November 1, 2001
66.	Organizational Charts (to the level of Directors) • Canadian Blood Services Head Office	February 14, 2002
67.	• Medical, Scientific & Clinical Management Department	February 14, 2002
68.	• Centres (Vancouver- 2001, Toronto-2002, Winnipeg-2001, Halifax)	2001 - 2002
69.	Human Resource Initiatives & Accomplishments	September 1998 – March 31, 2002
70.	Patient Services Program Recommendations	January 28, 2002
71.	Canadian Blood Services Job Descriptions • Manager, Collections	
72.	• Lab Technologist	
73.	• Lab Manager	
74.	• Manager, Quality Systems	
75.	• Quality Systems Associate	
76.	• Centre Director	
77.	• Executive VP, Operations	
78.	• Executive Manager, Manufacturing	
79.	• Lab Helper	
80.	Service Interruption Recovery Plan (Toronto)	
81.	Service Interruption Recovery Plan (Ottawa)	
82.	Final Report: Canadian Blood Services Response to the Recommendations	January 9, 2001

Canadian Blood Services CEO Reports

83.	CBS: CEO Report to Board on 2001 – 2002 Activities and Achievements.	May 16, 2002
84.	CEO Report January 1, 2002 – March 31, 2002	June 24, 2002
85.	CEO Reports	October - November 1999
86.	CEO Reports	September, 1999
87.	CEO Reports	August, 1999
88.	CEO Reports	June / July 1999
89.	CEO Reports	May, 1999
90.	CEO Reports	April, 1999
91.	CEO Reports	March, 1999
92.	CEO Reports	February, 1999
93.	CEO Reports	January, 1999
94.	CEO Reports	December, 1998
95.	CEO Reports	November, 1998

Canadian Blood Services Board and Executive Management Team Minutes of Meetings:

96.	Board of Directors Minutes of Meetings	April, 1998
97.	Board of Directors Minutes of Meetings	May, 1998
98.	Board of Directors Minutes of Meetings	June, 1998
99.	Board of Directors Minutes of Meetings	July, 1998
100.	Board of Directors Minutes of Meetings	August, 1998
101.	Board of Directors Minutes of Meetings	September, 1998
102.	Board of Directors Minutes of Meetings	October, 1998
103.	Board of Directors Minutes of Meetings	November, 1998
104.	Board of Directors Minutes of Meetings	December, 1998
105.	Board of Directors Minutes of Meetings	January, 1999
106.	Board of Directors Minutes of Meetings	February, 1999
107.	Board of Directors Minutes of Meetings	March, 1999
108.	Board of Directors Minutes of Meetings	April, 1999

109.	Board of Directors Minutes of Meetings	May, 1999
110.	Board of Directors Minutes of Meetings	June, 1999
111.	Board of Directors Minutes of Meetings	July, 1999
112.	Board of Directors Minutes of Meetings	August, 1999
113.	Board of Directors Minutes of Meetings	September, 1999
114.	Board of Directors Minutes of Meetings	October, 1999
115.	Board of Directors Minutes of Meetings	November, 1999
116.	Board of Directors Minutes of Meetings	December, 1999
117.	Board of Directors Minutes of Meetings	January, 2000
118.	Board of Directors Minutes of Meetings	February, 2000
119.	Board of Directors Minutes of Meetings	March, 2000
120.	Board of Directors Minutes of Meetings	April, 2000
121.	Board of Directors Minutes of Meetings	May, 2000
122.	Board of Directors Minutes of Meetings	June, 2000
123.	Board of Directors Minutes of Meetings	July, 2000
124.	Board of Directors Minutes of Meetings	August, 2000
125.	Board of Directors Minutes of Meetings	September, 2000
126.	Board of Directors Minutes of Meetings	October, 2000
127.	Board of Directors Minutes of Meetings	November, 2000
128.	Board of Directors Minutes of Meetings	December, 2000
129.	Board of Directors Minutes of Meetings	January, 2001
130.	Board of Directors Minutes of Meetings	February, 2001
131.	Board of Directors Minutes of Meetings	March, 2001
132.	Board of Directors Minutes of Meetings	April, 2001
133.	Board of Directors Minutes of Meetings	May, 2001
134.	Board of Directors Minutes of Meetings	June, 2001
135.	Board of Directors Minutes of Meetings	July, 2001
136.	Board of Directors Minutes of Meetings	August, 2001
137.	Board of Directors Minutes of Meetings	September, 2001
138.	Board of Directors Minutes of Meetings	October, 2001
139.	Board of Directors Minutes of Meetings	November, 2001
140.	Board of Directors Minutes of Meetings	December, 2001
141.	Board of Directors Minutes of Meetings	January, 2002
142.	Board of Directors Minutes of Meetings	February, 2002

143.	Board of Directors Minutes of Meetings	March, 2002
144.	Board of Directors Minutes of Meetings	May, 2002
145.	Board of Directors Briefing Binders	May 2-3, 2001
146.	Board of Directors Briefing Binders	June 14 - 15, 2001
147.	Board of Directors Briefing Binders	July 11 - 12, 2001
148.	Board of Directors Briefing Binders	August 15 - 16, 2001
149.	Board of Directors Briefing Binders	September 20 - 21, 2001
150.	Board of Directors Briefing Binders	October 24 - 25, 2001
151.	Board of Directors Briefing Binders	December 12 - 13, 2001
152.	Board of Directors Briefing Binders	February 13 - 15, 2002
153.	Board of Directors Briefing Binders	April 16 - 17, 2002
154.	Board of Directors Briefing Binders	May 15 - 17, 2002
155.	Canadian Blood Services Management Report	June 30, 2001
156.	Canadian Blood Services Management Report	July 31, 2001
157.	Canadian Blood Services Management Report	August 31, 2001
158.	Canadian Blood Services Management Report	September 30, 2001
159.	Canadian Blood Services Management Report	October 31, 2001
160.	Canadian Blood Services Management Report	November 30, 2001
161.	Canadian Blood Services Management Report	December 31, 2001
162.	Canadian Blood Services Management Report	January 31, 2002
163.	Canadian Blood Services Management Report	February 28, 2002
164.	Canadian Blood Services Management Report	February 28, 2002
165.	Canadian Blood Services Executive Management Team Minutes	January 2001 - April 2002
166.	Canadian Blood Services Executive Management Team Minutes	August 2000 - December 2002
167.	Canadian Blood Services Executive Management Team Minutes	September 1998 - December 2000
168.	Canadian Blood Services Executive Management Team In Camera Minutes	August, 2000 – December, 2002
169.	Canadian Blood Services Executive Management Team: State of the Blood System (confidential)	September, 1999

Canadian Blood Services Board Committee Minutes of Meetings:

170.	Finance & Audit Committee – Reference Binder Minutes of Meetings	May 1998 - May 2002
171.	Safety, Science & Ethics Committee - Reference Binder Minutes of Meetings	June 1998 - December 2002
172.	Human Resources Committee Minutes	September 1998 - February 2001
173.	Human Resources Committee In Camera Minutes	September 1998 - February 2001
174.	Executive Committee Minutes	November 1998 - November 2001
175.	Finance & Audit Committee Briefing Packages	May 15, 2002
176.	Finance & Audit Committee Briefing Packages	April 16, 2002
177.	Finance & Audit Committee Briefing Packages	Feb 13, 2002
178.	Finance & Audit Committee Briefing Packages	Dec 11, 2001
179.	Finance & Audit Committee Briefing Packages	Oct 23, 2001
180.	Finance & Audit Committee Briefing Packages	Sept 20, 2001
181.	Finance & Audit Committee Briefing Packages	Aug 14, 2001
182.	Finance & Audit Committee Briefing Packages	July 10, 2001
183.	Finance & Audit Committee Briefing Packages	June 14, 2001
184.	Finance & Audit Committee Briefing Packages	May 18, 2001
185.	National Liaison Committee Minutes - Summary of notes of the meeting of the National Liaison Committee held at the Chateau Laurier	October 22, 2001
186.	National Liaison Committee Minutes - Summary of notes of the meeting of the National Liaison Committee and Canadian Blood Services Board of Directors held at the Chateau Laurier	October 23, 2001
187.	National Liaison Committee Minutes - Summary of notes of the meeting of the National Liaison Committee chaired from the Cape Breton Room, Canadian Blood Services, Head Office	January 20, 2002
188.	National Liaison Committee Minutes – Canadian Blood Services Biological Product Deviation Cumulative summary	March 1-31, 2002

Canadian Blood Services Transformation Initiatives Documentation

189.	Transformation Overview: Presentation to the Performance Review Expert Panel	June 2002
190.	Canadian Blood Services: Donor Contact Centre: Business Case Study	October, 10, 2001
191.	Business Case Proposal: Information System for Canadian Blood Services. Bone Marrow Donor Registry	November, 27, 2000
192.	Canadian Blood Services: Financial Business Case for Plasma Self-Sufficiency. v1	June, 2000
193.	Interim Consolidation of Testing: Issues, Risks & Recommendations	March 9, 2002
194.	Business Case / Project Plan: Specialized Production of Frozen Products	February 28, 2002
195.	Test Centres and Transportation Review	September 15, 2000
196.	Business Case Summary Form: Windsor Consolidation	January 21, 2002
197.	Business Case Summary Form: New Saskatchewan Centre, Consolidation of Regina and Saskatoon Centres	January 18, 2002
198.	Canadian Blood Services Executive Management Team Discussion Document: Single versus Two Vendor for Transmissible Disease Testing. Version 1	March 11, 2002
199.	Canadian Blood Services Executive Management Team Discussion Document: Location for Canadian Blood Services Consolidated Laboratories	March 11, 2002
200.	Service Delivery Model – Detailed Design Projects Status Report	July 30, 2002
201.	Draft Transformation – Integration of Projects: Challenges and Plan	June 18, 2002
202.	Building a Better Blood System: Meeting the Needs for the Future (press release)	April 24, 2002
203.	Provincial Briefing Notes for April 24th, 2002 Canadian Blood Services Announcement: (NFL & Labrador; New Brunswick, Nova Scotia, Prince Edward Island, Ontario, Manitoba, Saskatchewan, Alberta, British Columbia, Northwest Territories, Nunavut)	June 11, 2002
204.	Canadian Blood Services Transformation Update: Support Services Design Workshop	March 26-27, 2001
205.	Recommended Detailed Design Projects: Steering	February 26, 2001

	Committee Meeting	
206.	2.00 Detailed Design Approach and Implementation Strategy: Steering Committee Meeting	February 12, 2001
207.	Business Case for Transformation at Canadian Blood Services: Benefits from Redesigning the Core Processes: Review of Partial Business Case Results with Transformation Steering Committee (confidential – not for distribution)	October 12, 2000
208.	Change Control Contract Scope – 2000-2001	

Canadian Blood Services Information Technology Information

209. Presentation – Managing the Information Services Portfolio
210. Corporate Services Information Systems – Breakdown of Budget for FY 2002-03
211. Corporate Services Information Systems – Capital Budget FY 2002-03
212. Information Services – Business Plan 2002-03 SAP HR/Payroll Project Update
213. SAP History within Canadian Blood Services
214. Business Solutions Team Unrelated Bone Marrow Donor Registry 2002 Overview
215. ESS Functional Demonstration
216. Presentation – Information Systems Disaster Planning

Canadian Blood Services Risk Management Information

217.	Canadian Blood Services By-Laws	Multiple dates
218.	Canadian Blood Services Letters Patent	February 2, 1998
219.	Mission Statement	September 26, 2001
220.	Vision Statement	September 26, 2001
221.	Value Statements	September 26, 2001
222.	Code of Ethical Conduct	September 26, 2001
223.	Quality Policy	April 29, 1999

224.	Risk Assessment Policy	April 18, 2000
225.	Risk Management Framework	Undated
226.	Risk Management Program Update	February, 2002
227.	Building a Foundation For The Future – Organizational Model and Delivery Systems Project – Phase I Summary	July, 1999
228.	Benchmark Performance Review – Facilities Consolidated Evaluation Report	June 1999
229.	Public Participation Task Force	April 14, 2000
230.	Public Participation Task Force Final Report	January 11, 2000
231.	CEO Report	April 17, 2002
232.	International Comparative Review of Blood Systems	November 2001
233.	Reviews of International Blood Systems	April 18, 2002
234.	Analysis of Health Canada Audit Observations	June 26, 2002
235.	Review of the Australian Blood Banking and Plasma Product Sector	2001
236.	The National Blood Service (UK) Report by the Comptroller and Auditor General	December, 2000
237.	Information Systems Problem Management Report	July 9, 2002
238.	Biological Product Deviation Summary	June 25, 2002
239.	Information Systems Problem Management Report	July 9, 2002
240.	Analysis of Health Canada Audit Observations	June 24, 2002
241.	Change Control	March 3, 2002
242.	Standard Operating Procedures (Various)	Multiple dates
243.	Directives (Various)	Multiple dates
244.	Canadian Blood Services Establishment Licenses	Multiple dates
245.	Consolidation of Testing – Approval Process and Risk Management Analysis	Multiple dates
246.	Realignment of Quality System Functions between Blood Centres and Head Office	February 21, 2001
247.	Proposal to the Executive Management Team for the Realignment of Quality Control Functions and the Standardization and Growth of Centre Quality Systems Units	December 10, 2001
248.	Internal Audit Services Risk-Based Audit Plan – Phase II – Consolidated Results, Analysis of Business Risks and Internal Audit Plan	October 3, 2001
249.	Supplier Qualification and Development Program	2001

250.	PEP (Progressive Excellence Program) Business Guide	April, 2000
251.	Transformation Communiqués	Multiple dates
252.	Good Manufacturing Practices for Schedule D Drugs – Part I: Biological Drugs	
253.	Draft Standards for Safety	July, 2000
254.	Quality of Human Blood and Blood Components	April 4, 2002
255.	Final Report of the Commission of Inquiry on the Blood System in Canada	November 26, 1997

Canadian Blood Services Financial Reporting Information

256.	2003 Budget and Corporate Plan Scenarios Briefing Notes and Supporting Material Prepared for Deputy Ministers of Health	2002
257.	Consolidated Financial Statements of Canadian Blood Services	March 2001 - May 2002
258.	Financial Audits and Non-Consolidated Financial Statements	March 1999 - March 2002
259.	Corporate Plans	1998 - 2005
260.	Shipment Report -	2001 - 2002
261.	Finance – Policies and Procedures (binder) contains: • Capital Assets	
262.	• Manual Payroll cheques/Advances	
263.	• Bank Reconciliation Format	
264.	• Month-end and Year-end Financial Closing Procedures	
265.	• Payroll Transfer Request	
266.	• New Journal Entry Process	
267.	• Bank Deposits	
268.	• Post Employee/Post Retirement Benefits	
269.	• Communication from HO – General Accounting	
270.	• Purchasing Cards	
271.	• CBS Month-end cut off schedule	
272.	• Employee Travel and Expense Policy	

273.	• CBS Fiscal Year-End Schedule –	March 31, 2002
274.	• 2001-2002 Year-end Activities	
275.	• Specific Guidelines	
276.	• Inventory Count – Instructions	
277.	• 2001-2002 Timetable for Year-End Cut-off	
278.	• 2001-2002 Required Working Papers	2001 - 2002
279.	• Contact List for Centres	
280.	• CBS – Various Forms for Reporting	
281.	Working copy of SOP 08 005 Errors/Accidents - Notification	
282.	Working copy of SOP 08 530 Reporting to Regulatory Authorities	
283.	Memo to Centre QASs re: Directive D99-012 Error/Accident and Donor Incident Reporting dated	July 9, 1999
284.	Memo to Master Copy Holders re: Directive D2002-001, Biological Product Deviation Report (BPDR)	February 22, 2002
285.	Memo to Master Copy Holders re: Directive D2002-005 Revision 1, New Bayer Plasma Codes for Recovered Plasma and Recovered Plasma Frozen Within 15 Hours	April 17, 2002
286.	Collections versus Target Statistics	April, 2002
287.	Management Reports - 12 months ended March 31, 2001	March 31, 2001
288.	Management Reports - 11 months ended February 28, 2002	February 28, 2002
289.	Extract from the minutes of the Executive & Governance Committee Meeting	February 13, 2002
290.	Information on Increased Cost Effectiveness	
291.	RBC & WB Discard Rate	
292.	Platelets, Leukocytes Reduced by Filtration (LRF) Discard Rate	
293.	Apheresis Platelet Discard Rate	
294.	Deloitte & Touche - January 24, 2002 - Nabi Contract Review	January 24, 2002
295.	Deloitte & Touche - Internal Audit Services Risk-Based Audit Plan	
296.	Phase II - Consolidated Results, Analysis of	

	Business Risks and Internal Audit Plan	
297.	Final Report - November 8, 2001	November 8, 2001
298.	Chart of Accounts	
299.	Canadian Blood Services (CBS) Issues Related to Working Capital Briefing Note	June 15, 2002
300.	PwC Consulting International Benchmarking Survey	2002
301.	Canadian Blood Services SAP HR/Payroll Proposal to Proceed	January, 2001
302.	Canadian Blood Services Agreement #149-99 with Bayer Corporation for Fractionated Products	April, 1998
303.	Canadian Blood Services Agreement #150-99 with Bayer Corporation for Fractionated Products	April 1, 2001
304.	Canadian Blood System Inventory Balance Reconciliation	March 31, 2002
305.	2001-2002 Fractionated Actual and Projected Results	
306.	Fractionated Actual and Projected Results	2000 - 2001
307.	Letter to Provincial / Territorial with Fractionation forecast	September 30, 2002
308.	Letter to Provincial / Territorial with Fractionation forecast	December 31, 2002
309.	Letter to Provincial / Territorial with Fractionation forecast	2001 - 2002
310.	Confirmation from the Lead Province for Fractionated Products	
311.	Canadian Blood Services Projection Costs for Fractionation	
312.	Operating Results for March 31, 2002	March 31, 2002
313.	Operating Results for March 31, 2001	March 31, 2001
314.	Test Performed Document	
315.	Ratio QA Staff to Production Staff in Canadian Pharmaceutical Industry and in North American Blood Bank Operators	November 7, 2001

Appendix B

Canadian Blood Services Performance Review Stakeholder Interviews

Canadian Blood Services Board of Directors

Gary Chatfield,	Board Chair
Fred Hyndman	Board Member, Chair of the Finance and Audit Committee
Doug Kinsella	Board Member, Chair, Safety, Science and Ethics Committee
Lynda Rankin	Board Member, Co-Chair, National Liaison Committee
Leah Hollins	Board Member, Chair, Human Resources Committee
Verna Skanes	Board Member, Vice–Chair of the Board

Canadian Blood Services: Past Leaders

Lynda Cranston	Past Chief Executive Officer
Ken Fyke	Past Board Chair

Canadian Blood Services Executive Management Team

Graham Sher	Chief Executive Officer
Ian Mumford	Executive Vice President, Operations
Watson Gale	Vice President and General Counsel
Pauline Port	Vice President, Corporate Services & Chief Financial Officer
John Johnston	Vice President, HR and Organizational Development
Wesley Rees	Executive Vice President, Safety & Performance Management
Dana Devine Heather Hume	Joint Acting Executive Vice President, Medical, Scientific & Clinical Management
Sophie de Villers	Executive Director, Policy and Planning

Canadian Blood Services Staff

Darren Praznik	Executive Director, Government Relations
Judie Leach-Bennett	Assistant Counsel to Watson Gale
Lois Atherton	Director, Operations Audit Group
Yanick Charles	Director, Process Quality
Brent Hart	Risk Management Officer
Tim Howe	Risk Management Director
Craig Ivany	Executive Director of Centre Operations
Tom Walker	Director of Regulatory Affairs
Rob Evans	Executive Director, Marketing
Marcel LeClair	Executive Director, Finance
Bev Atkinson	Centre Director, NFL / Labrador & Patient Services Special Project Manager
Jennifer Phillippe	Document Manager
Viki Jerke	Centre Director, Edmonton
Mathias Haun	Manager, Fractionation
Keith Buchanan	Fractionation Inventory Specialist
Vito Scalia	Director, National Testing Laboratory
Barbara Glick	Manager, Change Control
Jeff Moran	Executive Director, Information Technology
Heather Swayne	Director Strategic Information Systems
Brenda McLeod	Director SAP business system
Thomas Lyon	Manager SAP functional support
Steve Brule	Director Business Solution
Ruth Leard	Telerecruitment, Ottawa Centre
Debbie Cadelli	Supervisor, Administrative Support, Donor Services, Ottawa Centre
Kathy Gantz	Charge Technologist, Product Management, Ottawa Centre
Dianne Korim	Executive Director, Manufacturing

Canadian Blood Services Regional Centre Management Staff: Vancouver

Lisa dePaoli	Centre Director
Richard Blaine	Assistant Manager Donor Services
Irene Day	Collections Manager
Sean Hickey	Quality Systems Manager
Petra Welsh	Laboratory Manager

Canadian Blood Services Regional Centre Management Staff: Ottawa

Elaine Senack	Centre Director
Tony Giulivi	Medical Director
Diane Ayers	Donor Services Manager
Wendy Owens	Laboratory Manager
Darlene Neville	Quality Systems Associate
Kim Palmer	Collections Manager

Canadian Blood Services Regional Centre Management Staff: Toronto

Rene Naimans	Centre Director
Barbara Hannach	Medical Director
Marilee Kruspe	(Acting) Laboratory Manager, Production, Release & Distribution
Candy Lipton	Senior Collections Manager
Leigh Reynolds	Manager, Donor Services
Shirley Donaldson	Quality Systems Associate
Edna Zuber	Head Office Project Director Medical, Scientific and Clinical Management

Canadian Blood Services Regional Centre Management Staff: Halifax

Sue Smith	Centre Director
Joe Gauthier	Manager, Donor Services
Michelle Rogerson	Laboratory Manager
Marg Duguay	Manager, Clinic Operations
Helen Pye	Quality Systems Associate

Federal / Provincial / Territorial Representatives

David Reeleder	Ontario—Provincial / Territorial Contact
Phyllis Chuly	BC—Representative of lead province
Jeff Scott	Nova Scotia— Provincial / Territorial Contact
Tom Ward	Nova Scotia—Deputy Minister
George Peters	Saskatchewan— Provincial / Territorial Contact
Denise Canuel	Northwest Territories— Provincial / Territorial Contact
Joyce Thompson	Prince Edward Island – Provincial / Territorial Contact
Gerry White	Newfoundland – Provincial / Territorial Contact
Pierre Leveille	New Brunswick – Provincial / Territorial Contact
Gail Ure	Executive Director, Health Care Programs, Ontario Ministry of Health and Long-Term Care
Julia Hill	Health Canada Biologics & Genetic Therapies Directorate—Acting Director General
Dave Alexander	Alberta – Provincial / Territorial Contact
Jerry Teitel	National Blood Safety Council—Chair
Penny Chan	National Blood Safety Council--Coordinator

Consumer Groups

Tom Alloway	Canadian Hemophilia Association
Gerard Yetman	Canadian AIDS Society
Tim McClemont	Hepatitis C Society
Claude Renaud	Canadian Medical Association
Ray Berger	Canadian Transfusion Medicine Association

National Technical Working Group on Utilization Management

Susan Nahirniak	Medical Director, Transfusion Medicine, University of Alberta Hospital
Jeannie Callem	Sunnybrook & Women's College Health Sciences Centre, Ontario
John Freedman	St. Michael's Hospital, Ontario
Debra Lane	Medical Laboratory Director, Canadian Blood Services Winnipeg Centre Manitoba

VP Medicine / Chief Medical Officer

Perry Gray	Chief Medical Officer, Health Sciences Centre, Manitoba
John Shepard	Vancouver Coastal Health Authority, BC
Philip Gordon	Regional Medical Director of Labs, Capital Health Authority, Alberta

International Benchmark Survey

January 6, 2003

Purpose of the Survey

The Canadian Blood Services was established in 1998. When the organization was formed, it was agreed that a performance review would be conducted within five years to evaluate progress and identify areas for improvement. The Canadian government launched this review in May 2002.

A very important component of the review is international benchmarking. The purpose of the international benchmarking survey is to assess the comparative standings of CBS financial and operational performance, as compared to Hema-Quebec and blood suppliers in other countries with a similar service level, using a set of financial and operational performance indicators.

Blood Service Agencies Selected to Participate in the Survey
- Canadian Blood Services
- Hema-Quebec
- National Blood Service for England and North Wales
- Australian Blood Service
- Swedish Blood Service
- French Blood Service
- American Red Cross

Proposed Process and Timelines
- Questionnaires distributed to blood service agencies – June 17th
- Phone call from PwC to confirm delivery – June 18th
- Blood service agencies gather information and complete questionnaires – June 17 - July 5th
- E-mail from PwC to remind participants of survey deadline – June 28
- Return of completed surveys to PwC – July 5
- PwC collates survey results – July 8 -10
- Follow-up by PwC to review survey responses – July 10 – July 12

The attached survey that the participants will be receiving is divided into three parts:
- Part A: Profile of the blood service agency to get a sense of the scope and type of services provided
- Part B: Collection of data that will be used to calculate performance indicators that will provide information on the cost and resources required to operate the blood service agency as well as quality indicators.
- Definitions are provided for many of the data elements. Please review the definitions to ensure that data is completed is consistent with the other participants. If you are unsure of a definition or how the survey should be completed please contact Kelly Shum of PwC Consulting in Toronto at:

416-227-6363 extension 37428 or kelly.g.shum@ca.pwcglobal.com

Instructions

Go to the 'Part A Profile Entry' Tab and the 'Part B Data Entry' Tab and enter the information requested into the boxes:

Complete the survey in your local currency. Based on the dates provided for the data, the financial numbers provided will be converted to a common currency for comparison purposes.

Please see the definition tab in this file for the definitions of the terms used. It is essential that each blood agency participating in the survey include the same financial or statistical information in the same categories so that the information is comparable.

When you have completed the survey, please return it to Kelly Shum at the e-mail address above. We would appreciate receiving your completed survey by July 5th.

Based on the data collected through the survey, a number of performance indicators will be generated by PwC Consulting to inform the review of the Canadian Blood Service.

Thank you very much for taking the time to complete this survey. We look forward to following up with you and sharing the study results at a later date.

International Benchmark Survey

Profile of the Blood Service Agency

January 6, 2003

Part A Profile Entry

Instructions:

Please enter the information that is requested into ALL the blue boxes:

Answer:

Please enter 'Yes/No' answers into ALL the white boxes:

1) What is the name of the Blood Agency?

Answer:

2) From the list of functions provided below, please enter 'Yes' if your blood agency provides that function and 'No' if your blood agency does not provide that function:

Yes / No	**Function**
	Donor recruitment
	Collection of Whole Blood
	Plasmapheresis
	Platelet Collection by Apheresis/ Cytapheresis
	Homologous Blood Collection
	Autologous Blood Collection
	Donor Testing
	Patient Testing
	Processing of blood components
	Distribution of blood components to hospitals and other locations
	Storage of blood components
	Fractionation (purchased)
	Fractionation (local facilities for fractionation)
	Unrelated Bone Marrow Registry
	Research and Development
	Education
	Other (please list)

List all others that may apply:

3) Do you use Automated Blood Collection Devices (ABCD)?

☐ **Yes/No**

If yes, what is the proportion of collections completed with this method?

Answer:

4) What is the size of the population served?

Answer:

5) How many hospitals does your blood service agency distribute blood or blood products to?

Directly:

Total number of hospitals served by your blood service agency (I.e. including those that you do not ship to directly):

6) Does your blood service agency pay donors, or have donor incentives?

☐ **Yes/No**

If yes, please describe for what products and what the incentive is.

Answer:

7) Do hospitals have to pay for blood products received?

☐ **Yes/No**

If yes, under what circumstances?

Answer:

8) Does your blood agency receive back blood products from hospitals and re-issue?

Answer:

9) Do you have a blood assurance program[1]?

☐ **Yes/No**

[1] Blood assurance program sare programs where donors are not paid for their donation but they are assured that if they, or their family members, should need a blood transfusion in the future they will not have to pay.

10) Do you use commercially purchased blood products?

☐ **Yes/No**

If yes, which ones? From what countries?

Answer:

11) Is there use of prophylactic therapy for hemophiliacs in the area that you serve?

☐ **Yes/No**

12) Do you have a hemoglobin trigger?

☐ **Yes/No**

13) Does your agency use: (Please enter 'Y' for Yes and 'N' for No)

Y/N	**Standard**
☐	ISO 9000
☐	American Association of Blood Banks (AABB)
☐	Current Good Manufacturing Practices (cGMP)
☐	Title 21 of the Code of Federal Regulations
☐	Own standards developed by the agency
☐	No standards
☐	Other (Please describe)

Other:

14) What types of infectious disease screening tests does your blood service agency perform?
Please enter 'Y' if Yes your blood agency currently performs the particular test and the date it was implemented.
If there are additional tests that you are currently using for screening, please note them in the space below.

Yes/No	**Screening Test**	**Date Implemented**
	Hepatitis B Surface Antigen (HBsAg)	
	Antibodies to the Hepatitis B Core (Anti-HBC)	
	Antibodies to the Hepatitis C Virus (Anti-HCV)	
	Antibodies to the HIV, Types 1 and 2 (Anti-HIV-1,-2)	
	HIV-1 p24 Antigen	
	Antibodies to Human T-Lymphotropic Virus, Types I and II (Anti-HTLV-I, -II)	
	Syphilis	
	Nucleic Acid Amplification Testing (NAT) HIV	
	Nucleic Acid Amplification Testing (NAT) HBV	
	Nucleic Acid Amplification Testing (NAT) HCV	

Other:

15) Does your agency do pre-storage Leukoreduction on the units collected?

Yes/No

If so what percentage?

Answer:

16) Is your staff unionized?

Yes/No

If so, what percentage of the workforce is unionized?

Answer:

17) What is your latest fiscal year end (Month and Year)?

Answer:

International Benchmark Survey
October 18, 2002

Part B Data Entry

Instructions:

Please enter the month and the year(s) in which you are completing the information for (eg 04/2002) into the yellow boxes. ☐

Please enter the information that is requested into ALL the blue boxes: ☐

Ref #	Category	Most Recent Year Data Available	Year Before Most Recent Year Data Available
	Enter Year in Boxes		
	General		
1	Population (in 000's)		
2	# of Whole Blood Donors		
3	# of Whole Blood Donations		
4	# of times in the last fiscal year that hospital elective surgery was cancelled due to insufficient blood supply		
5	# of days in the last fiscal year that the Blood Centre was unable to ship Group O blood components as ordered		
6	# of Units Whole Blood Tested		
	Blood Components Collected		
7	# of litres of plasma collected for transfusion		
8	# of litres of plasma collected for further manufacturing		
9	# of units of platelet components collected		
	Units of Blood Components Collected		
10	# of units collected – Whole Blood		
11	# of units collected – Plasma through Plasmapheresis		
12	# of units collected – Platelets through Cytapheresis		
13	# of units collected – Other Blood Products		
14	# of units collected – All Blood Products Collected		
	Units of Useable Blood Components Available for Distribution		
15	# of useable units available for distribution – Red Blood Cells		
16	# of useable units available for distribution – Plasma through Plasmapheresis		
17	# of useable units available for distribution – Platelets through Cytapheresis		
	Units of Whole Blood Collected by Type		
18	# of units collected by the blood centre – Whole Blood Group A		
19	# of units collected by the blood centre – Whole Blood Group B		
20	# of units collected by the blood centre – Whole Blood Group AB		
21	# of units collected by the blood center – Whole Blood Group O		
	Units of Purchased Blood Components		
22	# of units purchased blood components – Whole Blood		
23	# of units purchased blood components – Red Blood Cells		
24	# of units purchased blood components – Plasma for transfusion		
25	# of units purchased blood components – Plasma for further manufacturing		
26	# of units purchased blood components – Platelet Components		
27	# of units purchased blood components – Other Blood components		
28	# of units of purchased blood components – All Blood components		

	Units of Blood Components and Fractionated Blood Products Distributed		
29	# of units distributed – Red Blood Cells		
30	# of units distributed – Plasma through Plasmapheresis		
31	# of units distributed – Platelets through Cytapheresis		
32	# of units distributed – Recombinant Factor VIIa		
33	# of units distributed – Recombinant Factor VIII		
34	# of units distributed – Recombinant Factor IX		
35	# of units distributed – Plasma-derived Factor VIII		
36	# of units distributed – Plasma-derived Factor IX		
37	# of units distributed – Albumin		
38	# of units distributed –IVIG		
39	# of units distributed – Other Commercial Fractionated Products		
40	# of units distributed – Other Blood Products		
41	# of units distributed – All Blood Products and Components		

	Outdated Blood Components at the Blood Centre	
42	# of units of Red Blood Cells Outdated at the blood center – Group A	
43	# of units of Red Blood Cells Outdated at the blood center – Group B	
44	# of units of Red Blood Cells Outdated at the blood center – Group AB	
45	# of units of Red Blood Cells Outdated at the blood center – Group O	

	Outdated Blood Components at the Hospital	
46	# of units of Red Blood Cells Outdated at the hospital – Group A	
47	# of units of Red Blood Cells Outdated at the hospital – Group B	
48	# of units of Red Blood Cells Outdated at the hospital – Group AB	
49	# of units of Red Blood Cells Outdated at the hospital – Group O	

	Returned or Recalled Blood Components to the Blood Agency	
50	# of units blood components returned or recalled other than outdating – Red Blood Cells	
51	# of units blood components returned or recalled other than outdating – Plasma	
52	# of units blood components returned or recalled other than outdating – Platelets	
53	# of units blood components returned or recalled other than outdating – Other Blood Products	
54	# of units blood components returned or recalled other than outdating – All Blood Products	

	Human Resources	
55	# of Staff Labour Hours	
56	# of Volunteer Labour Hours	

	Labour Hours	
57	# Labour Hours – Donor Recruitment	
58	# Labour Hours – Blood Collections – Whole Blood	
59	# Labour Hours – Blood Collections – Plasma through Plasmapheresis	
60	# Labour Hours – Blood Collections – Platelets through Cytapheresis	
61	# Labour Hours – Blood Collections – Other Blood Products	
62	# Labour Hours – Manufacturing/Processing	
63	# Labour Hours – Donor Blood Testing	
64	# Labour Hours – Storage and Distribution	
65	# Labour Hours – Quality Assurance and Quality Control	
66	# Labour Hours – Administration/Overhead – National Level	
67	# Labour Hours – Administration/Overhead – All Regional Blood Centres	
68	# Labour Hours – Other	
	Total Labour Hours	

		Most Current Year				Year Before Most Current Year			
Ref #	Enter Year in Boxes								
	Costs	Labour Costs	Medical Supply Costs	Other Costs	Total Costs	Labour Costs	Medical Supply Costs	Other Costs	Total Costs
	Blood Operations								
69	Cost – Donor Recruitment								
70	Cost – Blood Collections – Whole Blood								
71	Cost – Blood Collections – Plasma through Plasmapheresis								
72	Cost – Blood Collections – Platelets through Cytapheresis								
73	Cost – Blood Collections – Other Blood Products								
74	Cost – Manufacturing/Processing								
75	Cost – Donor Blood Testing								
76	Cost – Storage and Distribution								
	Other Functional Areas								
77	Cost – Quality Assurance and Quality Control								
78	Cost – Administration/Overhead – National Level								
79	Cost – Administration/Overhead – All Regional Blood Centres								
80	Cost – Unrelated Bone Marrow Donor Registry								
81	Cost – Patient Services								
82	Cost – Insurance								
83	Cost – Research & Development								
84	Cost – Other								
	Purchases Blood Products								
85	Cost – Purchased Fractionated Product – Recombinant Factor VIIa								
86	Cost – Purchased Fractionated Product – Recombinant Factor VIII								
87	Cost – Purchased Fractionated Product – Recombinant Factor IX								
88	Cost – Purchased Fractionated Product – Plasma-derived Factor VIII								
89	Cost – Purchased Fractionated Product – Plasma-derived Factor IX								
90	Cost – Purchased Fractionated Product – Albumin								
91	Cost – Purchased Fractionated Product – IVIG								
92	Cost – Purchased Fractionated Product – Other Products								
93	Cost – Purchased Non-Fractionated Products or Components								
94	**Total Costs**								

International Benchmark Survey
October 18, 2002
Definitions

Ref #	Terminology	Definition
	Total Blood Operating Cost	Includes the following:
		Total Cost – Donor Recruitment
		Total Cost – Blood Collections – Whole Blood
		Total Cost – Blood Collections – Plasma though Plasmapheresis
		Total Cost – Blood Collections – Platelets through Cytapheresis
		Total Cost – Manufacturing/Processing
		Total Cost – Donor Blood Testing
		Total Cost – Storage and Distribution
		Total Cost – Quality Assurance and Quality Control
		Total Cost – Administration/Overhead – National Level
		Total Cost – Administration/Overhead – All Regional Blood Centres
		Total Cost – Unrelated Bone Marrow Donor Registry
		Total Cost – Patient Services/Patient Testing
		Total Cost – Captive Insurance
		Total Cost – Research and Development
		Each of the above will be further explained in the definitions below:
	Unit of Blood Component Collected	The definition of a unit of Blood Component collected is a unit of whole blood collected or a unit of plasma collected through Plasmapheresis, or a unit of platelets collected through Apheresis Platelet Collection (Cytapheresis). Plasmapheresis and Apheresis Platelet Collection (Cytapheresis) would only be included if the country or organization participating in the survey collects blood products using Apheresis.
	# of useable units available for distribution	The number of useable units available for distribution is defined as the number of units of blood products that is collected and is available for distribution, excluding unusable units. Unusable units include products that are discarded or destroyed due to donors that do not qualify, or any other reasons that would render the product not usable. Units that are deemed unusable due to any other reason than outdating.
	Plasmapheresis	Plasma collection through the process of Apheresis
	Cytapheresis	Platelet collection through the process of Apheresis
	Regular Whole Blood Collection	Whole Blood that is collected and can be used by the general public and is not set aside for a specific person
	Autologous Whole Blood Collection	Whole Blood that is collected and is specifically set aside to only be used by the donor and not the general public
	Homologous Whole Blood Collection (Directed Whole Blood Collection)	Whole Blood that is collected and is specifically set aside to only be used by certain individuals and not the general public
	Insurance	Cost of insurance which includes the cost of Captive Insurance, premiums paid to insurance companies and any other costs that will insure themselves against claims for adverse events, accidents or deaths and etc. Captive Insurance is the cash reserved that is required by blood agency to have in case of an emergency.
	Administration/Overhead Costs	These would include items such as costs for Finance, Legal, Regulatory, Information Technology, Human Resources, Government Affairs, photocopying, printing, administrative labour costs and other travel costs. Some departmental costs that may be considered to be Administrative/Overhead are the Chief Executive Officer, Chief Financial Officer, Chief Information Officer, Legal, Human Resources and other related management costs.
	General	
1	Population (in000's	Total population serviced by your blood agency in 000's
2	# of Whole Blood Donors	Includes the # of Blood Donors that currently donate blood in a given year
3	# of Whole Blood Donations	Includes the # of donations received in a given year
4	# of times in the last fiscal year that hospital elective surgery was cancelled due to insufficient blood supply	Includes the number of non-emergency cancelled surgery's which had resulted because blood was not available
5	# of days in the last fiscal year that the Blood Centre was unable to ship Group O blood Products as ordered	Includes the number of days the Blood Centre did not have enough supply or was not logistically able to ship Group O blood products
6	# of Units Whole Blood Tested	Includes all units of Whole Blood that has been tested using such tests as P24 Antigen and NAT testing

	Blood Components Collected	**Definition**
7	# of litres of plasma collected for transfusion	Includes all plasma that has been collected for transfusion purposes
8	# of litres of plasma collected for further manufacturing	Includes all plasma that has been collected for further manufacturing purposes such as making fractionated products with the collected plasma units
9	# of units of platelet components collected	Includes all units of platelet components that has been collected using any method

	Units of Blood Components Collected	
10	# of units collected – Whole Blood	Includes the # of units of regular, autologous and directed Whole Blood that is collected
11	# of units collected – Plasma through Plasmapheresis	Includes the # of units of Plasma that is collected through Plasmapheresis
12	# of units collected – Platelets through Cytapheresis	Includes the # of units of Platelets that is collected through Cytapheresis
13	# of units collected – Other Blood Products	Includes the # of units of blood products that is collected which is not: Whole Blood, Plasma that is collected through Plasmapheresis (eg Plasma collected through Recovered Plasma), Platelets that is collected through Cytapheresis (eg Platelets collected through Random Donors) or Fractionated Blood Products.
14	# of units collected – All Blood Products Collected	Total number of units of all blood products that is collected, not including Fractionated Blood Products

	Units of Useable Blood Components Available for Distribution	
15	# of useable units available for distribution – Red Blood Cells	Usable Units of Red Blood Cells available for distribution is defined as the number of units of blood products that is available for distribution, excluding unusable units. Unusable units include products that are discarded or destroyed due to donors that do not qualify, or any other reasons that would render the product not useable. Units that are deemed unusable due to any other reason than outdating.
16	# of useable units available for distribution – Plasma through Plasmapheresis	Usable Units of Plasma using Plasmapheresis that is available for distribution is defined as the number of units of blood products that is available for distribution, excluding unusable units. Unusable units include products that are discarded or destroyed due to donors that do not qualify, or any other reasons that would render the product not usable. Units that are deemed unusable due to another reason than outdating.
17	# of useable units available for distribution – Platelets through Cytapheresis	Usable Units of Platelets using Cytapheresis that is available for distribution is defined as the number of units of blood products that is available for distribution, excluding unusable units. Unusable units include products that are discarded or destroyed due to donors that do not qualify, or any other reasons that would render the product not usable. Units that are deemed unusable due to any other reason than outdating.

	Units of Whole Blood Collected by Type	
18	# of units collected by the blood center – Whole Blood Group A	Includes number of Red Blood Type A collected at the blood centre
19	# of units collected by the blood center – Whole Blood Group B	Includes number of Red Blood Type B collected at the blood center
20	# of units collected by the blood center – Whole Blood Group AB	Includes number of Red Blood Type AB collected at the blood center
21	# of units collected by the blood center – Whole Blood Group O	Includes number of Red Blood Type O collected at the blood center

	Units of Purchased Blood Components		
22	# of units purchased blood products – Whole Blood	A	Includes the number of units of Whole Blood that is purchased from an outside vendor
23	# of units purchased blood products – Red Blood Cells	B	Includes the number of units of Red Blood Cells that is purchased from an outside vendor
24	# of units purchased blood products – Plasma for transfusion	C	Includes the number of units of Plasma that is for transfusion that is purchased from an outside vendor
25	# of units purchased blood products – Plasma for further manufacturing	D	Includes the number of units of Plasma that is for further manufacturing (such as fractionation) that is purchased from an outside vendor
26	# of units purchased blood products – Platelet Components	E	Includes the number of units of Platelet Components that is purchased from an outside vendor
27	# of units purchased blood products – Other Blood components	F	Includes the number of units of Other Blood Products that is purchased from an outside vendor
28	# of units of purchased blood products – All Blood components	G	Includes all blood products purchased (A+B+C+D+E+F=G)

	Units of Blood Components and Fractioned Blood Products Distributed	
29	# of units distributed – Red Blood Cells	Includes the number of units of Red Blood Cells that is distributed to places outside of the blood organization, such as hospitals
30	# of units distributed – Plasma through Plasmapheresis	Includes the number of units of Plasma that had been collected through Plasmapheresis which is distributed to places outside of the blood organization, such as hospitals
31	# of units distributed – Platelets through Cytapheresis	Includes the number of units of Platelets that had been collected through Cytapheresis which is distributed to places outside of the blood organization, such as hospitals
32	# of units distributed – Recombinant Factor VIIa	Includes the number of units of Recombinant Factor VIIa that is distributed to places outside of the blood organization, such as hospitals, clinics and etc

33	# of units distributed – Recombinant Factor VIII	Includes the number of units of Recombinant Factor VIII that is distributed to places outside of the blood organization, such as hospitals, clinics and etc.
34	# of units distributed – Recombinant Factor IX	Includes the number of units of Recombinant Factor IX that is distributed to places outside of the blood organization, such as hospitals, clinics and etc.
35	# of units distributed – Plasma-derived Factor VIII	Includes the number of units of Plasma-derived Factor VIII that is distributed to places outside of the blood organization, such as hospitals, clinics and etc.
36	# of units distributed – Plasma-derived Factor IX	Includes the number of units of Plasma-derived Factor IX that is distributed to places outside of the blood organization, such as hospitals, clinics and etc.
37	# of units distributed – Albumin	Includes the number of units of Albumin that is distributed to places outside of the blood organization, such as hospitals, clinics and etc.
38	# of units distributed –IVIG	Includes the number of units of IVIG that is distributed to places outside of the blood organization, such as hospitals, clinics and etc.
39	# of units distributed – Other Commercial Fractionated Products	Includes the number of units of other Commercial Fractionated Products such as Antithrombin, CI Esterase Inhibitor, Factor XI, Fibrinogen, Protein C and others that is distributed to places outside of the blood organization, such as hospitals, clinics and etc.
40	# of units distributed – Other Blood Products	Includes the number of units of blood products that is not Red Blood Cells or fractionated products that is distributed to places outside of the blood organization, such as hospitals, clinics and etc.
41	# of units distributed – All Blood Products	Total number of units of blood products distributed to places outside of the blood organization, such as hospitals, clinics and etc.

	Outdated Blood Components at the Blood Centre	**Definition**
42	# of units of Red Blood Cells Outdated at the blood center – Group A	Includes number of Red Blood Type A cells that has expired and has exceeded its useful life or shelf life at the blood center
43	# of units of Red Blood Cells Outdated at the blood center – Group B	Includes number of Red Blood Type B cells that has expired and has exceeded its useful life or shelf life at the blood center
44	# of units of Red Blood Cells Outdated at the blood center – Group AB	Includes number of Red Blood Type AB cells that has expired and has exceeded its useful life or shelf life at the blood center
45	# of units of Red Blood Cells Outdated at the blood center – Group O	Includes number of Red Blood Type O cells that has expired and has exceeded its useful life or shelf life at the blood center

	Outdated Blood Components at the Hospital	
46	# of units of Red Blood Cells Outdated at the hospital – Group A	Includes number of Red Blood Type A cells that has expired and has exceeded its useful life or shelf life at the hospital
47	# of units of Red Blood Cells Outdated at the hospital – Group B	Includes number of Red Blood Type B cells that has expired and has exceeded its useful life or shelf life at the hospital
48	# of units of Red Blood Cells Outdated at the hospital – Group AB	Includes number of Red Blood Type AB cells that has expired and has exceeded its useful life or shelf life at the hospital
49	# of units of Red Blood Cells Outdated at the hospital – Group O	Includes number of Red Blood Type O cells that has expired and has exceeded its useful life or shelf life at the hospital

	Returned or Recalled Blood Components to the Blood Agency	
50	# of units blood components returned or recalled other than outdating – Red Blood Cells	Includes the number of units of Whole Blood returned or recalled other than outdating which may be caused by items such as mislabeling or defects in the product
51	# of units blood components returned or recalled other than outdating – Plasma	Includes the number of units of Plasma returned or recalled other than outdating which may be caused by items such as mislabeling or defects in the product
52	# of units blood components returned or recalled other than outdating – Platelets	Includes the number of units of Platelets returned or recalled other than outdating which may be caused by such items as mislabeling or defects in the product
53	# of units blood components returned or recalled other than outdating – Other Blood Products	Includes the number of units of Other Blood Products that are not Whole Blood, Plasma or Platelets that is returned or recalled other than outdating which may be caused by items such as mislabeling or defects in the product
54	# of units blood components returned or recalled other than outdating – All Blood Products	Total number of units of Blood Products that is returned or recalled other than outdating which may be caused by items such as mislabeling or defects in the product.

	Human Resources	
55	# of Staff Labour Hours	The number of hours that paid staff worked for the blood agency
56	# of Volunteer Labour Hours	The number of hours that unpaid workers worked for the blood agency

	Labour Hours	**A Labour Hour is equivalent of one hour of paid work that is performed on behalf of the Blood Agency**
57	# Labour Hours – Donor Recruitment	Includes the number of hours required for Donor Recruitment
58	# Labour Hours – Blood Collections – Whole Blood	Includes the number of hours required for Whole Blood Collection
59	# Labour Hours – Blood Collections – Plasma through Plasmapheresis	Includes the number of hours required for Plasma Collection
60	# Labour Hours – Blood Collections – Platelets through Cytapheresis	Includes the number of hours required for Platelets Collection
61	# Labour Hours – Blood Collections – Other Blood Products	Includes the number of hours required for Other Blood Products that is now Whole Blood, Plasma or Platelets Collection
62	# Labour Hours – Manufacturing/Processing	Includes the number of hours required for Manufacturing/Processing
63	# Labour Hours – Donor Blood Testing	Includes the number of hours required for Donor Blood Testing

64	# Labour Hours – Storage and Distribution	Includes the number of hours required for Blood Storage and Distribution
65	# Labour Hours – Quality Assurance and Quality Control	Includes the number of hours required for Quality Assurance and Quality Control
66	# Labour Hours – Administration/Overhead – National Level	Includes the number of hours required for Administration/Overhead at the National or head office level
67	# Labour Hours – Administration/Overhead – All Regional Blood Centres	Includes the number of hours required for Administration/Overhead encompassing all of the regional blood centers
68	# Labour Hours – Other	Includes the number of hours required for all other functions not listed above

	Total Costs	**Definition**
	Total Costs include all items in the following list:	-Donor Recruitment
		-Blood Collections – Whole Blood
		-Blood Collections – Plasma through Plasmapheresis
		-Blood Collections – Platelets through Cytapheresis
		-Blood Collections – Other Blood Products
		-Manufacturing/Processing
		-Donor Blood Testing
		-Storage and Distribution
		-Quality Assurance and Quality Control
		-Administration/Overhead – National Level
		-Administration/Overhead – All Regional Blood Centres
		-Unrelated bone Marrow Donor Registry
		-Patient Services/Patient Testing
		-Insurance
		-Research and Development
	Total Cost – Labour	A. Includes all labour costs such as salary costs, benefit costs, overtime costs, employee severance costs, taxable benefit costs, non-taxable benefit costs, vacation costs, sick and other leave costs, worker compensation costs, bonus costs, training and certification costs, honorarium costs, temporary staff costs, pension costs, relocation and transfer costs and other labour related costs
	Total Cost – Medical Supplies	B. Includes all medical supplies costs such as collection supplies (eg vacuum tubers, swab sticks, iodine, alcohol, gauge squares, bandages, lancets capillary tubes, alcohol wipes, cotton balls, sodium citrate, needles, transfer packs, blood warming bags, and surge plasma exchange coupler, collection containers, collections labels, collection bags, plasma bowls, plasma harnesses, plasma needles, sodium citrate and etc.
	Total Cost – Other Operating	C. Includes all other operating costs that affect the blood operations and which is not associated with labour or medical supplies such as promotional and advertising costs, legal services costs, photocopying and printing costs, phone costs, computer costs, travel costs, property costs, waste disposal costs and etc D. Total Costs of All Operating (D) = Total Cost of Labour (A) + Total Cost of Medical Supplies (B) + Total Cost of Other Operating (C)
	Total Cost – All Operating	Includes all operating costs that affect the blood operations which are all Labour, Medical Supplies and Other Costs that are in the following functional areas:

	Total Costs Functional Area	Total Costs include all Labour, Medical Supplies and Other Costs associated with each Functional Area
69	Total Cost – Donor Recruitment	Total Costs incurred for recruiting donors such as labour and non-labour costs such as promotion and advertising costs, cost of blood donor clinics such as hall rental, catering costs and janitorial fees, donor card costs, donor awards costs, volunteer expenses (e.g. meals, travel, blood donor telephone recruitment costs and etc.), donor pin costs, promotional material (e.g. keychains, mugs, pens, t-shirts, etc.), and etc.
70	Total Cost – Blood Collections – Whole Blood	Total costs incurred for collection whole blood such as the labour costs for collecting whole blood, medical supply costs such as collection containers, collection labels, collection supplies such as vacuum tubers, swab sticks, iodine, alcohol, gauge squares, bandages, lancets, capillary tubes, alcohol wipes, cotton balls, sodium citrate, needles, transfer packs, blood warming bags, and etc. As well Total costs include all related management costs of conducting Blood Collections
71	Total Cost – Blood Collections – Plasma through Plasmapheresis	Total costs incurred for collection of plasma such as labour costs for collecting plasma and medical supply costs of plasma bags, plasma labels and etc. As well Total costs include all related management costs of conducting Blood Collections.
72	Total Cost – Blood Collections – Platelets through Cytapheresis	Total costs incurred for collection of platelets such as labour costs for collecting platelets and medical supply costs of bags, labels and etc. As well Total costs include all related management costs of conducting Blood Collections
73	Total Cost – Blood Collections – Other Blood Products	Total costs incurred for collection of all other blood products that are not Whole Blood, Plasma through Plasmapheresis or Platelets through Cytapheresis. As well Total costs include all related management costs of conducting Blood Collections.
74	Total Cost – Manufacturing/Processing	Total costs incurred for manufacturing, processing, storage and distribution of blood products such as the labour costs and non-labour costs. Non-labour costs include the cost of rent for storage, distribution vehicles, and processing center costs.

75	Total Cost – Donor Blood Testing	Total costs incurred for testing donor blood such as the labour for testing blood and medical supplies. Includes items such tests as P24 Antigen, HbsAG, HCV, test kits, NAT and all related management of these test costs.
76	Total Cost – Storage and Distribution	Total costs incurred for the storage and the distribution of blood products. These costs would include the cost of the storage space, shipping costs, loop back costs, trace back costs and medical overview costs.
77	Total Cost – Quality Assurance and Quality Control	Total cost of Quality Control of all distributed products
78	Total Cost – Administration/Overhead – National Level	Total costs incurred for overhead costs which include other office costs such as photocopying, printing costs, administrative labour costs and other travel costs for the National or Head Office Level. These costs relate to Chief Executive Officer, Chief Financial Officer, Chief Information Officer, Legal, Human Resources personnel, accounting payroll and other related management costs.
79	Total Cost – Administration/Overhead – Regional Blood Centre Level	Total costs incurred for overhead costs which include other office costs such as photocopying, printing costs, administrative labour costs and other travel costs for all of the regional blood center levels or the sum of the individual blood centers not including costs for the Head Office. These include all of the center overhead costs and all other related management costs at the center.
80	Total Cost – Unrelated Bone Marrow Donor Register	Total costs incurred for unrelated bone marrow donor registry such as the search consultant costs, laboratory costs and travel for donor costs.
81	Total Cost – Patient Services	Total costs incurred for Patient Services and Patient Testing such as the labour cost to conduct these services and the medical testing costs
82	Total Cost – Insurance	Cost of insurance which includes the cost of Captive Insurance, premiums paid to insurance companies and any other costs that will insure themselves against claims for adverse events, accidents or deaths and etc. Captive Insurance is the cash reserved that is required by blood agency to have in case of an emergency.
83	Total Cost – Research & Development	Total costs incurred for research and development such as the labour costs, medical supplies and other related costs.
84	Total Cost – Other	Total Costs that are not include in lines 69 to 83 are not fractionated products
85	Cost – Purchased Fractionated Product – Recombinant Factor VIIa	Cost of Recombinant Factor VIIa
86	Cost – Purchased Fractionated Product – Recombinant Factor VIII	Cost of Recombinant Factor VIII
87	Cost – Purchased Fractionated Product – Recombinant Factor IX	Cost of Recombinant Factor IX
88	Cost – Purchased Fractionated Product – Plasma-derived Factor VIII	Cost of Plasma-derived Factor VIII
89	Cost – Purchased Fractionated Product – Plasma-derived Factor IX	Cost of Plasma-derived Factor IX
90	Cost – Purchased Fractionated Product – Albumin	Cost of Albumin
91	Cost – Purchased Fractionated Product – IVIG	Cost of IVIG
92	Cost – Purchased Fractionated Product – Other Products	Cost Other Fractionated Products
93	Cost Purchased Non-Fractionated Products or Components	Cost of Non-Fractionated Products or Components
94	Total Costs	Total Cost of all operations including lines 69-94

Appendix D:

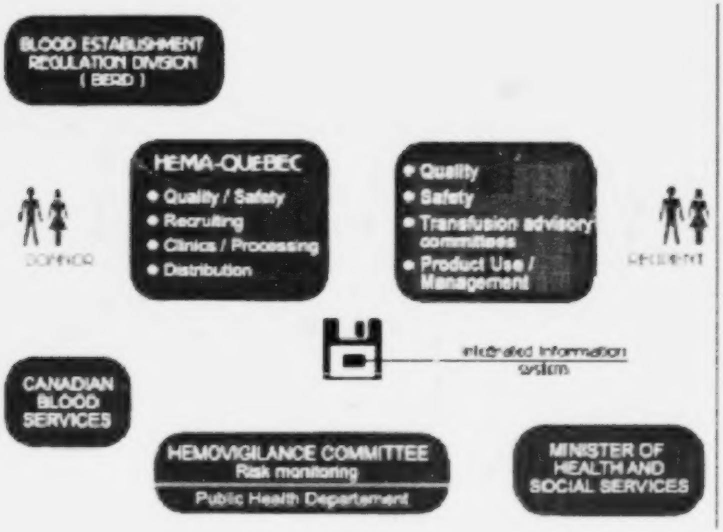
Description of Blood Service Agencies (other than CBS) that Participated in the International Benchmarking Survey

Hema-Quebec

Hema-Quebec is Quebec's blood management system. The population of Quebec is 7.4 million. The total blood service cost for 2001/02 was approximately $205.3 million.

Out of the Gélineau and Krever reports, the Quebec Minister of Health and Social Services announced the creation of Hema-Quebec on March 30, 1998 as part of the reorganization of this province's blood management system. Hema-Quebec has no direct dependence on the government and is fully integrated into the province's health-care network.

Hema-Quebec's organizational structure consists of a board of directors representing all stakeholders in the blood system from recipients, volunteers, hospitals, transfusion doctors, public health, business and academia. The board of directors is supported by three advisory committees: the Medical and Scientific Advisory Committee; the Safety Advisory Committee and the Liaison committee. Hema-Quebec is linked to the Canadian system through partnership agreements such as plasma and fractionated product exchanges established with the Canadian Blood Services (CBS). A computer link is established between the donor banks of these two agencies.


BLOOD ESTABLISHMENT REGULATION DIVISION (BERD)
HEMA-QUEBEC
• Quality / Safety
• Recruiting
• Clinics / Processing
• Distribution
DONNOR
• Quality
• Safety
• Transfusion advisory committees
• Product Use / Management
RECIPIENT
integrated information system
CANADIAN BLOOD SERVICES
HEMOVIGILANCE COMMITTEE
Risk monitoring
Public Health Departement
MINISTER OF HEALTH AND SOCIAL SERVICES

Hema-Quebec is responsible for recruiting donors, organizing blood donor clinics and providing the hospitals with quality blood and blood products. Hema-Quebec delivers blood components directly to the 117 hospitals in Quebec. The distinctive feature of Quebec's blood management system is the direct link between Hema-Quebec and its clients, the hospitals. Transfusion medicine committees are being set up to ensure that medical practice is in compliance with international guidelines and standards. Hospitals that with the expertise in transfusion medicine have been selected as designated hospitals and are in charge of transfusions in their region.

The MAK- PROGESA system, has been in place in Quebec since late 1999. It links Hema-Quebec, the hospitals and the Hemovigilance Committee. This program was deployed in late 1999. Quebec hospitals use the hospital version of PROGESA to manage their blood banks.

Hema-Quebec currently outsources NAT testing but plans to begin providing this testing in-house in 2003.

Hema-Quebec's fractionation products are purchased through CBS on a cost recovery basis.

American Red Cross

The American Red Cross, a humanitarian organization, is led by volunteers whose mission is to provide relief to victims of disasters and help people prevent, prepare for and respond to emergencies. It accomplishes this mission through Chapter Services, Biomedical Services and national headquarters operations.

Biomedical Services is fiscally and operationally separate from Chapter Services and consists. The American Red Cross blood service is part of Biomedical Services. It serves 38 states in the continental United States and Puerto Rico. The size of the population served is approximately 287.9 million. The blood centers in each region collect, process and distribute blood and blood products to hospitals throughout the United States. Over 6.7 million donations were collected in the last fiscal year. The American Red Cross performs NAT-HCV and NAT-HIV. They plan to begin performing NAT-HBV in 2003. HIV-1 p24 antigen testing is also performed.

The American Red Cross accepts blood back from hospitals according to specific return policies.

In addition to core blood service functions, the American Red Cross also provides:

- Perioperative Autologus cell salvage services
- Photopheresis services

- Therapeutic Apheresis services
- Peripheral Blood Stem Cell program.

The American Red Cross does not pay donors, however they do offer nominal incentives within FDA guidelines.
The American Red Cross Board of Governors formulates policy and delegates governance authority to local chapter and Blood Services region volunteer boards of directors, consistent with corporate policy and external regulatory bodies.

Virtually all of the expenses of Biomedical Services are covered by revenues from the sale of products and services. National headquarters provides management oversight to the chapters and Biomedical Services, as well as providing corporate services in areas such as insurance, finance, audit, legal, human resources, communication and marketing and fund raising. National headquarters also coordinates the international activities of the organization.

Red Cross operating funds come from three main funding sources: contributions, revenues from products and services and other sources. Total Red Cross operating revenues and gains for fiscal 2000-01 were $2.743 billion.

United Kingdom National Blood Services

The National Blood Service (NBS) is the England and North Wales national blood organization. It serves a population of 47.7 million. The total blood service cost for 2001/02 was approximately $263.6 million excluding commercially purchased products.

As an integral part of the National Health Service (NHS), the NBS is responsible for the delivery of blood, blood components, blood products and tissues from 15 blood centres to anywhere in England and North Wales. The NBS provides blood and blood products to over 300 hospitals. (There are also a number of small, private hospitals that receive their blood through partnerships with NHS Trust Hospitals.) Hospitals pay for the blood and products they receive. This charge is not for the blood itself but covers the cost of managing the service and is determined by a national group managed by the Department of Health (National Commissioning Group for Blood). Additionally, the NBS charges for components for research (from waste material). Once blood is delivered to the hospitals it is only accepted back by the NBS if an investigation is required such as suspected bacterial contamination (i.e. not for re-issue).

In addition, to core blood services functions, NBS also provides:

- Bone and Tissue services including cord blood banking
- Cytapheresis
- Therapeutic Apheresis including progenitor stem cell collection and processing
- Reagent supply
- Histocompatibility and Immunogenetics
- Red cell serology

- Antenatal Testing
- International Blood Group Reference Laboratory (IBGRL)

The NHS was set up just over 50 years ago and is now the largest blood organisation in Europe. The NHS is funded by the taxpayers of England and North Wales and is accountable to Parliament. It is managed by the Department of Health.

Every year, the NBS collects, tests, processes, stores and issues approximately 2.5 million blood donations. Plasma is purchased commercially from U.S. sources. NAT-HCV testing is performed but NAT-HIV and HIV-1 p24- antigen testing are not performed.

It is dependent on voluntary donations from the general public. NBS has a number of other functions such as continually carrying out new research into improving the safety of blood, providing specialist medical advice and clinical support to hospitals, and training transfusion machine specialists.

Sweden

Sweden is self sufficient in blood products and there are more than 470,000 registered donors in the country. About 250,000 of those donors donate blood at least once a year. More than five per cent of the population are registered donors. There are about 90 Blood Centres in Sweden, most of them found at hospitals and run by the County Councils. A few of the Blood Centres have moved out from the hospitals to make it easier to donate blood (e.g. at shopping centres). There are also eleven blood buses, which operate in cities, country villages and also visit larger companies.

Sweden does not have a centralized single blood organization that manages the entire blood system. The blood system in Sweden is managed regionally. The departments of transfusion medicine in the counties of Dalarna, Gävleborg, Uppsala, Västmanland and Örebro (the Uppsala-Orebro region) participated in the international benchmarking survey for this review. The size of the population served is 1.38 million. The total blood service cost for 2001/02 was approximately $127 million.

In addition to the core blood services functions, the Uppsala-Orebro blood service also provides:

- Collection of autologous and allogeneic stem cells
- Therapeutic hemapheresis
- Granulocytapheresis for transfusion
- Therapeutic phlebotomy
- Compatibility testing and issuing of blood
- Immunohematological investigation in complicated serological cases and for pregnant women
- Consultant services during all hours.

The blood service does not perform any NAT testing nor does it perform HIV-1 p24 antigen testing.

The blood service provides blood and blood products directly to two university hospitals, three county hospitals and eleven minor hospitals.

Almost all laboratory services in the health care system in Sweden have a fee system – this includes blood and blood products. Hospitals are charged for the blood and blood products they receive. Within a county, there is no transfer of money for blood or laboratory services. Between counties, however, money is transferred. The fee is established to cover the costs of the blood establishments.

All blood centers in the region are situated within hospitals. As a result, the blood service will accept blood back for re-issue from the hospitals in which they are located. Blood that is transferred from one hospital to another outside the transport system of the blood centers is not accepted for re-issuing unless a unbroken coldchain can be documented.

Appendix E

Hospital Survey For the Canadian Blood Services Performance Review

Introduction and Purpose

The Canadian Blood Services was established in 1998. When the organization was formed, it was agreed that a performance review would be conducted within five years to evaluate progress and identify areas for improvement. The provincial and territorial governments (except Quebec) jointly launched this review in May 2002 and commissioned PwC Consulting to carry out the review.

Hospitals are customers and key stakeholders of the Canadian Blood Service. The data collected from this survey will be used to develop an understanding of the extent to which the Canadian Blood Service is meeting the requirements of hospitals across Canada.

Your survey responses will be kept confidential. Results will only be reported in an aggregate format and individual hospitals or respondents will not be identified by name. The survey results will be extremely helpful for future planning and will benefit both the Canadian Blood Service and the hospitals.

Objectives

- To give hospitals an opportunity to provide input to the review
- To understand hospital requirements for blood components
- To assess hospital satisfaction levels with the provision of blood components
- To identify opportunities for improvement

Survey Organization and Instructions for Completion

The survey has been designed to be as easy and fast to complete as possible. Almost all of the questions are close-ended questions. However, there will be a need to gather some data from your records or databases. The survey is organized under the following headings:

Demand Planning – determining of product need
Order and Inventory Management – how blood components are ordered, tracked and managed
Performance Measurement – product quality, product wastage, reporting feedback
Customer Service – timeliness, quality and service

You can enter your responses directly into the Microsoft word document (e.g. by putting an x in the check boxes)

Survey Return

The deadline for survey returns is **Wednesday, July 10, 2002**. We recognize that the timeline is short, but we would greatly appreciate your participation in this process. When you have completed the survey, please return it to Lynda Annall via e-mail or fax. Contact information is provided below:

Lynda Annall
PwC Consulting
10 York Mills Road, Suite 400
Toronto, Ontario M2P 2C9
E-mail: lynda.j.annall@ca.pwcglobal.com
Fax: 416-941-8419

Questions

If you have any questions about this survey, please contact **Michele Jordan, Project Manager at 905-804-7204.**

First, we would like to begin by asking you several questions related to how you determine your blood service requirements and the frequency of those orders and how they are communicated.

Demand Planning

1. Please rank in order of importance those factors which are most important in determining your hospital's target inventory for key blood components. (1 = most important)

a) For Red Blood Cells

Ranking	**Factors**
	Operating room availability
	Hospital bed closures
	Physician/Staff Holiday Schedule
	Seasonal variations
	Elective procedures
	Historical utilization
	Number of regular patients with medical conditions that requires regular use of blood products (e.g. haemophiliacs)
	Other (Define) ________________
	Other (Define) ________________

b) For Plasma

Ranking	**Factors**
	Operating room availability
	Hospital bed closures
	Physician/Staff Holiday Schedule
	Seasonal variations
	Elective procedures
	Historical utilization
	Number of regular patients with medical conditions that requires regular use of blood products (e.g. haemophiliacs)
	Other (Define) ________________
	Other (Define) ________________

c) For Platelets

Ranking	Factors
	Operating room availability
	Hospital bed closures
	Physician/Staff Holiday Schedule
	Seasonal variations
	Elective procedures
	Historical utilization
	Number of regular patients with medical conditions that requires regular use of blood products (e.g. haemophiliacs)
	Other (Define) ______________________
	Other (Define) ______________________

2. How frequently and by what method does your hospital routinely order blood components?

FREQUENCY

☐ Daily basis
☐ 2 or 3 times per week
☐ Once per week
☐ Once per month
☐ Less than once per month

METHOD

☐ Phone
☐ Fax
☐ E-mail
☐ Information Systems
☐ Other

3. Does your hospital receive requests from other hospitals for blood products in your inventory?

Yes ☐ No ☐

If yes, what is the frequency of these requests?

☐ Daily
☐ Weekly
☐ Monthly
☐ Less than monthly

Also, do you plan for these additional needs when you forecast blood component demand?

Yes ☐ No ☐

4. If you know that blood is in short supply, do you ever order more than you actually need to ensure receiving required quantities?

   Yes ☐ No ☐

5. What is your level of customer satisfaction with the acquisition of fractionated products?

   ☐ Very Good
   ☐ Good
   ☐ Neutral
   ☐ Poor
   ☐ Very Poor
   ☐ Don't know

Once you determine your product needs, we would like to understand how orders are tracked, transported and managed.

Order and Inventory Management

6. By contacting the CBS, can you track the status of your order after you've ordered it?

   Yes ☐ No ☐

7. What is the typical delivery (response) time for routine orders? (Please check)

   ROUTINE

   ☐ Less than 12 hours
   ☐ 12 to 24 hours
   ☐ 25 to 48 hours
   ☐ 2 to 4 days
   ☐ More than 4 days

8. What method of transportation does your hospital use the most for the transport of urgent orders?

   ☐ Taxi
   ☐ Ambulance
   ☐ Police
   ☐ Courier
   ☐ Other ________________________________

9. Does your hospital use a computerized inventory system?

Yes ☐ No ☐

If Yes, what is the name of the system? ______________________

10. Does your hospital use a computerized system for tracking how blood components are actually used?

Yes ☐ No ☐

If Yes, what is the name of the system? ______________________

11. How does your hospital track the receipt of blood components through to the patient that receives the blood component?

☐ Computerized system
☐ Manual system
☐ Combination of computerized and manual systems
☐ Do not track the receipt of blood components through to the recipient

12. Does your hospital have a process/mechanism in place to monitor and manage the utilization of blood products (e.g. a Blood Utilization Committee, a Transfusion Officer, etc)?

Yes ☐ No ☐

Briefly describe the process/mechanism ______________________

13. How does your hospital monitor the aging of products?

☐ Computerized system
☐ Manual system
☐ Combination of automated and manual systems
☐ Other ______________________

14. Typically, what percent of blood products cannot be used because of spoilage (this does not include outdated or expired product)? _____ %

15. Please complete the following table to help us understand the type and volumes of blood components you typically have on-site.

Product	Product stored on site?	Target Inventory Level (days)	Average age of Blood product stored on-site (days)				Number of units discarded last year
			Group A	**Group B**	**Group AB**	**Group O**	
Red Blood Cells	Yes ☐ No ☐						
Platelets	Yes ☐ No ☐						
Fresh Frozen Plasma	Yes ☐ No ☐						
Cryoprecipitate	Yes ☐ No ☐						
Cryosupernatant	Yes ☐ No ☐						

Now we would like to ask you several questions related to how well the current blood supply system is performing.

Performance Measurement

16. Do order lead times (from order placement to delivery) consistently meet your requirements?

Yes ☐ No ☐

If No, please explain. ____________________

17. On average, what percentage of the time does your hospital receive its full order of Type "O" group blood?

Rh +	**Rh –**
☐ 96 – 100%	☐ 96 – 100%
☐ 91 – 95 %	☐ 91 – 95%
☐ 86 – 90%	☐ 86 – 90%
☐ 80 – 85%	☐ 80 – 85%
☐ 76 – 79%	☐ 76 – 79%
☐ Less than 75%	☐ Less than 75%

18. Annually, approximately how many elective surgeries requiring blood components are cancelled as a direct result of a blood product shortage? Please answer for as many years as you have data that is readily available.

	Elective surgeries cancelled
Fiscal Year 2002 (April to June)	____________________
Fiscal Year 2001	____________________
Fiscal Year 2000	____________________
Additional years _____	____________________

19. On an annual basis, approximately how many platelet orders allocated to transfusion patients are reduced as a direct result of a blood component shortage? Please answer for as many years as you have data that is readily available.

	Number of Platelet Order Reductions
Fiscal Year 2002 (Year to Date as of May 31)	____________________
Fiscal Year 2001	____________________
Fiscal Year 2000	____________________
Additional years _____	____________________

20. Approximately what percentage blood products ordered is unusable due to improper processing, packaging or handling?

☐ Less than 1%
☐ 1 - 5%
☐ 5 - 10%
☐ 10- 20%
☐ More than 20%

21. Is there a clear mechanism in place to relay blood product quality issues to your local Blood Centre?

Yes ☐ No ☐

22. How would you best describe your local Blood Centre's ability to handle blood product quality issues?

- ☐ No mechanism in place to handle
- ☐ Records issue but no noticeable action is taken
- ☐ Records issue but actions are slow
- ☐ Actions are taken initially but no follow-up
- ☐ Action is swift and product quality follow-up occurs for a defined period
- ☐ Pro-active communication to ensure no product quality issues exist
- ☐ Other (describe) ____________________

23. In the past year, how often have you had meetings with representatives of your local Blood Centre?

- ☐ No meetings
- ☐ 1 to 3 meetings
- ☐ 4 to 6 meetings
- ☐ 7 to 9 meetings
- ☐ 10 or more meetings

24. What type of support does your local Blood Centre provide to your hospital?

- ☐ Educational sessions on blood bank issues (e.g. ordering, handling, storage of blood products)
- ☐ Educational sessions on transfusion medicine
- ☐ Educational sessions on utilization management
- ☐ Information sessions on new and emerging products and research
- ☐ Other (explain) ____________________

25. If you checked any of the types of support identified in question 24 above, how would you rate the overall effectiveness of these sessions?

- ☐ Very Good
- ☐ Good
- ☐ Neutral
- ☐ Poor
- ☐ Very Poor
- ☐ Don't know

26. What is your level of awareness of the respective roles and responsibilities of the local Blood Centre and your hospital?

Yes ☐ No ☐ Don't know ☐

27. Since September1998, has your local Blood Centre or the Canadian Blood Service ever contacted your hospital to get input on your level of satisfaction with the service they provide?

☐ Yes If yes, in what year were you last contacted? _____
☐ No
☐ Don't know

28. What changes would you like to see to improve customer service and efficiency in the Canadian Blood Services supply chain?

____

____

____

Now we would like to ask you for your opinion on how well the Canadian Blood Services is meeting your needs from a customer service perspective.

Timeliness	**Very Good**	**Good**	**Neutral**	**Poor**	**Very Poor**
Responds in a timely manner on CBS related enquiries	☐	☐	☐	☐	☐
Provides products in a timely manner	☐	☐	☐	☐	☐
Is time sensitive with minimal delays in processing orders	☐	☐	☐	☐	☐
Provides appropriate information and status of orders in a timely manner	☐	☐	☐	☐	☐
How has timeliness changed since 1998?	☐ **Improved**	☐ **No Change**	☐ **Worsened**		

Product Quality	Very Good	Good	Neutral	Poor	Very Poor
Continuously monitors process to ensure integrity of components	☐	☐	☐	☐	☐
Identifies opportunities for improvement	☐	☐	☐	☐	☐
Is effective in fulfilling current mandate	☐	☐	☐	☐	☐
How has quality changed since 1998?	☐ **Improved**		☐ **No Change**		☐ **Worsened**

Customer Service	Very Good	Good	Neutral	Poor	Very Poor
Local Blood Centre is a valuable resource	☐	☐	☐	☐	☐
Has a structured and effective order management process	☐	☐	☐	☐	☐
Is able to consistently deliver "full orders" of blood components on time	☐	☐	☐	☐	☐
Is responsive to customer needs and therefore is a good "supplier"	☐	☐	☐	☐	☐
Works to ensure customer requirements are consistently met	☐	☐	☐	☐	☐
How has service changed since 1998?	☐ **Improved**		☐ **No Change**		☐ **Worsened**

Finally, we would like to ask you to identify your organization for demographic purposes and to allow us to contact you for clarification, if required.

Respondent Name:

Respondent Position:

Hospital Name:

Thank you very much for cooperating in this review. Please feel free to make any additional comments you wish regarding this survey questionnaire or the Canadian Blood Service supply chain in the space below

Comments: _____

Appendix F

Canadian Blood Services Performance Review Hospital Survey Results

Executive Summary

Objectives

A hospital survey was carried out by the consulting team between June 17th and July 17th, 2002 as part of the performance review of the Canadian Blood Services (CBS). The objectives of the survey were to:

a. Give hospitals an opportunity to provide input into the review
b. Understand hospital requirements for blood components
c. Assess hospital satisfaction levels with the provision of blood components
d. Identify opportunities for improvement

Content and Results

The survey was divided into sections relating to:

- demand planning
- order and inventory management
- performance measurement
- customer service

A copy of the survey questionnaire is attached as Appendix E.

Key findings were as follows:

Demand Planning:

- Key factors for hospitals in determining their target inventory levels of red blood cells and plasma were historical usage and the number of regular patients with medical conditions requiring the regular use of blood products. The key factor for hospitals in determining their target inventory levels of platelets were the number of regular patients with medical conditions requiring the regular use of platelets.

- The majority of respondent hospitals (31%) order blood products two or three times a week. The most popular method of ordering blood components is by fax (42%), followed by telephone (28%).

- Fifty one percent of respondents indicated they receive requests from other, smaller hospitals for blood products. Most respondents however, do not take these requests into account when they forecast blood component demand.

- The majority of respondents (80%) reported their level of satisfaction with the acquisition of fractionated blood products was, at least good.

Order and Inventory Management

- The majority (88%) of respondents can track the status of an order once placed with the CBS.

- The most common method of transportation used by hospitals for urgent orders was taxi (23%), followed by bus and courier (18% each).

- Forty percent of hospitals used a computerized inventory system, with the most popular being Meditech (52%); Thirty six percent of hospitals use a computerized system for tracking how blood is used, with Meditech being the most popular).

- Fifty percent of respondents have a mechanism in place to monitor and manage the utilization of blood products, the most popular being monthly reviews (33%) followed by Blood Transfusion Committees (30%).

- The majority of hospitals (60%) monitor the aging of blood by manual methods.

- There is room for improvement with respect to the discard rate for products, particularly platelets. Approximately 17% were discarded last year.

Performance Measurement

- Eighty three percent of hospitals say that lead times meet their requirements.

- A small percentage (two percent) of hospitals had to cancel elective surgeries because of blood shortages in 2002. This is a decrease from previous years.

- The number of hospitals having to reduce platelet orders allocated to transfusion patients as a direct result of blood shortages has been constant (at seven percent) since 2000.

- The majority of respondents (91%) reported less than one percent of blood products ordered are unusable due to improper processing, packaging or handling.

- Eighty six percent of hospitals indicated that their local Blood Centres have a clear mechanism in place to deal with blood product quality issues with a majority finding those mechanisms to be satisfactory.

- Blood Centres provide support in a number of ways including educational sessions, written information and telephone or faxed communications. Sixty two percent of respondents who indicated they received support found it to be useful.

- Respondents provided a number of suggestions for improvement of customer service and efficiency. The most common suggestions were better transport services, better administrative communication, more educational sessions and better access.

Customer Satisfaction

- The majority of respondents rated Blood Centres as either good or very good when it came to issues of timeliness, product quality and customer service. However, a majority of respondents also felt that there had been no change in service since 1998 for any of these three indicators.

Methodology

Survey Sample

A total universe of 547 hospitals in all provinces and territories, excluding Quebec, were identified as receiving Leuko RBC shipments between 31 March, 2001 and 31 March, 2002. Smaller hospitals receiving blood components from larger hospitals with no direct shipments from the CBS were excluded from the survey.

A minimum sampling of 365 hospitals of the total 547 was required assuming a planned 40% response rate to ensure statistical validity with a 5 to7% confidence interval.

For the purpose of administering the survey, quotas were established to ensure representation from each province and territory based on the number of hospitals directly serviced by the CBS. To ensure an adequate survey respondent representation from the smaller provinces and territories, all hospitals receiving CBS products were surveyed at a 100% sampling frame, with the remaining larger provinces being sampled at a 60% interval.

Individual hospitals to be surveyed in the larger provinces where identified by a stratified sampling methodology with a randomly generated starting point. The hospital survey sampling by province and territory and response rate is summarized below.

Province/Territory	Hospitals that receive Leuko RBC Shipments	# of Hospitals to be surveyed	# of Responses	% Response Rate
Alberta (AB)	67	40	33	83%
British Columbia (BC)	88	53	43	81%
Manitoba (MB)	72	43	27	63%
New Brunswick (NB)	22	22	15	68%
Newfoundland & Labrador (NF)	28	28	8	29%
Nova Scotia (NS)	22	22	14	64%
Northwest Territories (NT)	4	4	3	75%
Nunavut Territory (NU)	2	2	1	50%
Ontario (ON)	166	100	46	46%
Prince Edward Island (PI)	8	8	2	25%
Quebec (QC)	1	1	0	0%
Saskatchewan (SK)	76	46	27	59%
Yukon Territory (YT)	1	1	1	100%
TOTALS	**557**	**371**	**220**	**59%**

Administration and response rate

The survey was self-administered by the hospitals. It was delivered to the identified hospitals' laboratory managers for completion. The laboratory managers returned the survey to PwC Consulting by means of electronic e-mail or fax.

A total of 220 hospitals responded to the self-administered survey for an overall 59% response rate.

A. Hospital Survey Results

Demand planning

The survey asked respondents questions concerning their blood service requirements, the frequency of their orders and how they communicate orders to CBS. In summary, the factor sited most frequently as the "most important" in establishing target inventory levels for red blood cells and plasma is historical utilization.

For platelets, the factor most often ranked as the most important in establishing target inventory levels is the number of regular patients with medical conditions who require the regular use of these products. Approximately one half of the responding hospitals order blood components daily or 2-3 times per week, with the majority (75%) ordering by telephone or fax. Ten percent indicated they over order blood components during periods of known blood shortages to ensure adequate delivery.

Determining hospital target inventory levels: "most important factors"

Respondents were asked to rank, in order of importance, those factors considered when determining hospital target inventory levels for key blood components. With respect to red blood cells, the responses revealed three major factors that determine hospitals' target inventory for key blood products, namely, historical usage (39% of respondents said it was the most important factor), the number of regular patients with medical conditions who require the regular use of blood products (32% of respondents said it was the most important factor), and the number of elective procedures (seven percent of respondents said it was the most important factor). A number of hospitals indicated that requirements for emergency supplies was also important in determining their target inventory levels.

The results were similar in respect of plasma (34% for historical utilization, 22% for the number of regular patients with medical conditions who require the regular use of blood products, and five percent for the number of elective procedures).

For platelets however, the number of regular patients with medical conditions who require the regular use of blood products played a much greater role than historical utilization (45% of respondents indicated that this was the most important determining factor). A number of hospitals also noted that they did not keep an inventory of platelets on site but ordered them as and when required.

Other factors considered less important in determining demand for all three types of product related to variables that showed predictability in consumption or use. These factors were operating room availability and seasonal variations.

The responses are summarized in the table below. The numbers in brackets represent the number of respondents who ranked the factor in question as being the most important factor.

Factors used by hospitals to determine target inventory levels	**Percentage of hospitals ranking factor as most important**		
	Red Blood Cells	**Plasma**	**Platelets**
Historical Utilization	39% (85)	34% (74)	9% (19)
# of regular patients with medical condition requiring regular use of blood products	32% (79)	22% (48)	45% (98)
Other	13% (28)	11% (25)	15%(32)
Elective Procedures	7% (16)	5% (11)	5% (10)
Operating room availability	7% (16)	6% (14)	2% (5)
Seasonal Variations	3% (6)	2% (4)	2% (4)
Hospital bed closures	1% (86)	1% (2)	1% (2)
Physician/Staff Holiday Schedule	1% (2)	1% (2)	1% (1)

The category titled “other” includes no inventory kept on site/order as needed; emergency supply; availability of supplies, distance from supplier or nearest CBS Centre; keep on hand for patients with specific needs; and ambiguous.

Requirements Ordering and Communications: Frequencies and Methods

Responses to questions concerning frequency of ordering and method of communicating requirements to the CBS reveal that the majority of hospitals responding to the survey (31%) order two or three times per week. A total of 207 hospitals provided this information. The most popular method of ordering blood components among responding hospitals is by fax (42%), followed by telephone (28%). A total of 165 hospitals provided this information.

The following table shows the frequency with which respondents order blood components.

Number of Respondents	Percentage	Frequency
43	20%	Daily basis
69	31%	2 or 3 times per week
36	16%	Once per week
41	19%	Once per month
18	8%	Less than once per month

The following table shows the method by which respondents order blood components.

Number of Respondents	Percentage	Method
93	42%	Fax
61	28%	Telephone
9	4%	Other
2	1%	Information Systems
0	0%	E-mail

A table detailing the frequency of ordering blood components by province stratified by hospital size is summarized below.

Province	Number of Hospitals	Hospital Size as per units Shipped	Frequency of Ordering Blood Components					
			Daily	2-3/week	1/week	1/month	<1/month	No Response
AB	27	Small <2,000	2	3	7	8	7	
	0	Medium 2001 - 5000						
	2	Large 5000 - 10000	1	1				
	1	Very Large > 10,000	1	1				
	3	Don't Know	1				1	1
BC	22	Small <2,000	1	9	3	9		
	12	Medium 2001 - 5000	4	7				1
	2	Large 5000 - 10000	2					
	3	Very Large > 10,000	3					
	17	Don't Know	1		2	9	4	1
MB	5	Small <2,000	1	2	2	1		
	2	Medium 2001 - 5000	1	1				
	2	Large 5000 - 10000	1	1				
	0	Very Large > 10,000						
	4	Don't Know				1		3
NB	8	Small <2,000		4	4			
	2	Medium 2001 - 5000	2					
	0	Large 5000 - 10000						
	5	Very Large > 10,000	2	3				
	0	Don't Know						
NF	6	Small <2,000	1	2	2	1		
	0	Medium 2001 - 5000						
	0	Large 5000 - 10000						
	2	Very Large > 10,000	1		1			
	0	Don't Know						

Province	Number of Hospitals	Hospital Size as per units Shipped	Frequency of Ordering Blood Components					
			Daily	2-3/week	1/week	1/month	<1/month	No Response
NS	14	Small <2,000	1	8	4	1		
	0	Medium 2001 - 5000						
	0	Large 5000 - 10000						
	0	Very Large > 10,000						
	0	Don't Know						
NT	3	Small <2,000			1	2		
	0	Medium 2001 - 5000						
	0	Large 5000 - 10000						
	0	Very Large > 10,000						
	0	Don't Know						
NU	1	Small <2,000	1					
	0	Medium 2001 - 5000						
	0	Large 5000 - 10000						
	0	Very Large > 10,000						
	0	Don't Know						
ON	24	Small <2,000	1	14	4	2	1	2
	12	Medium 2001 - 5000	6	5				1
	1	Large 5000 - 10000	1					
	1	Very Large > 10,000	1					
	7	Don't Know	2	4	1			
PE	1	Small <2,000			1			
	0	Medium 2001 - 5000						
	0	Large 5000 - 10000						
	0	Very Large > 10,000						
	1	Don't Know		1				
SK	23	Small <2,000	2	4	3	7	5	2
	1	Medium 2001 - 5000	1					
	0	Large 5000 - 10000						
	1	Very Large > 10,000	1					
	1	Don't Know	1					
YT	0	Small <2,000						
	2	Medium 2001 - 5000	1		1			
	0	Large 5000 - 10000						
	0	Very Large > 10,000						
	0	Don't Know						
	220		**44**	**70**	**36**	**41**	**18**	**11**

Requests: Smaller Hospitals

Of the total 220 hospitals that responded to the survey, 112 (51%) indicated that they receive requests from other hospitals for blood products in their inventory. The majority of these small hospitals (52%) request product less than monthly while 21% request product monthly and 19% request product weekly. (Only two hospitals did not respond to this question.) Six percent of the hospitals receiving requests for blood components from smaller hospitals receive them on a daily basis.

These additional blood components are typically not taken into consideration by the larger hospitals when they forecast blood component demand. Seventy two percent of hospitals that say they receive requests from smaller hospitals reported that they do not plan for these additional needs when they forecast their blood component demand.

Over ordering

Of the total hospitals in the survey, only 10% indicated that they would over order blood components when blood is in short supply to ensure receiving required quantities. The majority (86%) do not order more than needed to ensure receiving required quantities. A total of 212 hospitals responded to this question.

Below we present a detailed analysis by province and hospital size for those 23 hospitals indicating that they over-order blood components when in short supply.

Province	Number of Hospitals Over Ordering		Hospital Size			
			Small	Med	Large	Very Large
		% Over Ordering	<2,000	2,001 - 5000	5001 - 10,000	>10,000+
AB	3	9	1	1	1	
BC	3	6.9	1		1	1
MB	1	3.7		1		
NB	2	13.3		1		1
NF	2	25	2			
NS	3	21.4	3			
NT	0	0				
NU	0	0				
ON	7	15.2	5	1	1	
PE	0	0				
SK	2	7.4	2			
YT	0	0				
	23					

Customer satisfaction

Survey respondents were asked their level of customer satisfaction with regard to the acquisition of fractionated products. Responses were on a Likert scale ranging from very good to very poor. The majority of respondents indicated that they were satisfied, with 38% reporting their level of satisfaction to be very good and 42% reporting it to be good. Only two percent of respondents indicated that their level of satisfaction was poor. Five percent of respondents did not know. A total of 208 respondents gave an answer to this question.

A detailed analysis for customer satisfaction regarding acquisition of fractionated blood products by province and hospital size is shown below. The Likert Scale codes used are as follows:

NR = No Response VG = Very Good G = Good N= Neutral P = Poor VP = Very Poor

Province	Number of Hospitals	Number of Annual Units Received	VG	G	N	P	VP	NR
AB	26	Small <2,000	9	13				4
	2	Medium 2001 - 5000	1					1
	2	Large 5000 - 10000	1	1				
	1	V.L. > 10,000	1					
	2	Don't Know	2					
BC	23	Small <2,000	10	11	1			1
	12	Medium 2001 - 5000	3	5	3			1
	2	Large 5000 - 10000		1		1		
	3	V.L. > 10,000		2		1		
	3	Don't Know			2	1		
MB	22	Small <2,000	7	10	1			4
	3	Medium 2001 - 5000	2	1				
	0	Large 5000 - 10000						
	1	V.L. > 10,000		1				
	1	Don't Know	1					
NB	11	Small <2,000	4	7				
	2	Medium 2001 - 5000	1	1				
	0	Large 5000 - 10000						
	2	V.L. > 10,000	1	1				
	0	Don't Know						
NF	7	Small <2,000	4	3				
	0	Medium 2001 - 5000						
	0	Large 5000 - 10000						
	1	V.L. > 10,000		1				
	0	Don't Know						

Province	Number of Hospitals	Number of Annual Units Received	VG	G	N	P	VP	NR
NS	12	Small <2,000	9	3				
	2	Medium 2001 - 5000	2					
	0	Large 5000 - 10000						
	0	V.L. > 10,000						
	0	Don't Know						
NT	3	Small <2,000	1					2
	0	Medium 2001 - 5000						
	0	Large 5000 - 10000						
	0	V.L. > 10,000						
	0	Don't Know						
ON	24	Small <2,000	6	11	3			4
	12	Medium 2001 - 5000	4	5	2	1		
	2	Large 5000 - 10000	1		1			
	1	V.L. > 10,000		1				
	7	Don't Know	1	5	1			
PE	0	Small <2,000						
	0	Medium 2001 - 5000						
	0	Large 5000 - 10000						
	0	V.L. > 10,000						
	2	Don't Know	2					
SK	25	Small <2,000	11	8	3			3
	0	Medium 2001 - 5000						
	0	Large 5000 - 10000						
	1	V.L. > 10,000						1
	1	Don't Know		1				
YT	1	Small <2,000	1					
	0	Medium 2001 - 5000						
	0	Large 5000 - 10000						
	0	V.L. > 10,000						
	0	Don't Know						
TOTAL	**220**		**96**	**92**	**17**	**4**	**0**	**21**

B. Order and Inventory Management

The survey sought respondents' input on the issues of tracking, transporting and managing blood component inventory. Overall, the responses indicate a high level of satisfaction with the supply chain between customer and CBS. While 88% of hospitals are able to track the status of an order once placed with the CBS, only 40% have any type of computerized inventory system and as a result 57% of hospitals manage aging of blood components through manual methods (three percent did not answer this question). A calculated estimated discard rate for blood components ranged from 3.4% for cryosupernatant to 4.8% for red blood cells, 9.8% for cryoprecipitate and 17.8% for platelets. These figures indicate potential opportunities for improvement in terms of enhanced product utilization management.

Routine orders

The majority (88%) of respondents indicated that they could track the status of an order once placed with the CBS (211 hospitals provided this information). Approximately half of the hospitals (55%) indicated that the typical delivery response time from order placement to delivery for a routine order was between 12 and 24 hours, while 35% reported a delivery response time of less than 12 hours. A total of 214 hospitals provided this information. When asked for comments on areas for improvement 28 hospitals (13%) identified issues with third party service providers who transported and delivered product from CBS regional centres to hospitals. The major issue related to untimely delivery of product or restrictions on the frequency of product delivery due to airline or bus schedules. A total of 120 hospitals responded to this question.

Urgent orders

The most common method of transportation used by hospitals for transport of urgent orders was taxi (23%), followed by bus and courier (both 18%) and plane (7%), police (4%), ambulance (0.5%), and other (9%). The category titled other includes transportation by families, hospital maintenance staff, and local volunteer drivers. A total of 178 hospitals provided information concerning transportation.

Computerized inventory system

Forty percent of respondent hospitals indicated that they use a computerized inventory system, while 57% indicated that they did not. The most common system was Meditech (52%), with other systems used including Hemocare (4%), Triple G/Triple G LIS (7%), Soft Bank (6%), Cerner LIS (3%), Eclypsis (3%) and Health Vision (3%) and TriWin (2%). One percent of respondents did not answer or gave an ambiguous response when asked if they had a computerized inventory system.

A detailed analysis by province for those hospitals using a computerized inventory system is summarized below.

			Hospital Size				
Province	**Inventory System In Use**	**Number of Hospitals**	**Small <2,000**	**Medium 2,001-5,000**	**Large 5,000-10,000**	**Very Large >10,000**	**Don't Know**
AB	Yes	11	5	1	2	1	2
	No	20	20				
BC	Yes	20	3	10	2	3	2
	No	22	20	1			1
MB	Yes	0					
	No	27	22	3		1	1
NB	Yes	12	9	2		1	
	No	3	2			1	
NF	Yes	4	3			1	
	No	4	4				
NS	Yes	5	5				
	No	9	9				
NT	Yes	0					
	No	3	3				
ON	Yes	30	9	11	2	1	7
	No	16	15	1			
PE	Yes	1					1
	No	1					1
SK	Yes	5	3			1	1
	No	21	21				
YT	Yes	1	1				
	No	0					
TOTAL		**218**	**156**	**29**	**7**	**10**	**16**

Computerized tracking system

In terms of tracking how blood is actually used, only 36% of hospitals indicated that they used a computerized system for this purpose. A total of 213 hospitals provided a response to this question. Of those hospitals that did use a computerized system for tracking how blood is used, the most common system was Meditech (54%), followed by Triple G/Triple G LIS (8%), Hemocare and Soft Bank (5%), Cerner LIS (4%), and Tri Win (3%).

A majority (50%) of hospitals indicated that tracking of the receipt of blood components through to the recipient that receives the specific blood component at the individual unit level is done through a manual system. Only 20% of hospitals reported using a computerized system, while 23% reported using a combination of both computerized and manual systems. Only one percent reported that they do not track the receipt of blood components through to the recipient. A total of 208 hospitals provided this information.

Hospitals were asked whether they have a process or mechanism in place to monitor and manage the utilization of blood products. A total of 214 hospitals responded to this question. A small majority (50%) reported that they did have such a process or mechanism in place, while 47% reported that they did not. The methods used by those hospitals that did respond positively are set out in the following table. The numbers in brackets represent the number of respondents for each process/mechanism.

Process/Mechanism to Manage Blood Product Utilization	**Percentage of responding hospitals using processes /mechanisms**
Monthly Review	33% (34)
Blood Transfusion Committee	29% (30)
Blood Utilization Committee	14% (14)
Meetings (specified/unspecified)	6% (6)
Regular inventory/tracking system	6% (6)
Other transfusion staff (specified)	4% (4)
Monitored on a regular basis	3% (3)
Reviewed by pathologist	3% (3)
Pharmacy Therapeutic Committee	2% (2)

Note: The percentages do not add up to 100 as some respondents gave more than one answer.

Monitoring aging of blood products

Hospitals were asked how they monitor the aging of blood products. A total of 207 hospitals provided a response. The majority of hospitals (60%) indicated that they monitor the aging of blood by manual methods. Only 11% of hospitals use a computerized system, while 21% use a combination of automated and manual systems.

Respondents were asked what percentage of blood products typically cannot be used because of spoilage (not including outdated or expired blood product). The majority of respondents (35% of the total population or 75% of the hospitals that responded to the question) indicated that they would typically discard less than one percent of blood products because of spoilage. One respondent noted that they would discard no blood ordered for specialities, but would discard 60% of that ordered for emergencies. Only 103 hospitals provided a response to this question.

Respondents were also asked to provide the number of units discarded in the last year (including outdated or expired product). The following table summarizes the results on a national basis.

Product	**Stored on site?** **(All Responses)**	**Total Units Shipped (All Provinces)**	***Estimated number of units discarded per year**	***Estimated % discarded (of total units shipped)**
Red Blood Cells	*Yes:* 85% *No:* 12%	718,632	12,698	4.8
Platelets	*Yes:* 14% *No:* 76%	320,397	20,856	17.8
Cryoprecipitate	*Yes:* 33% *No:* 57%	39,589	1437	9.8
Cryosupernatant	*Yes:* 5% *No:* 83%	30,361	281	3.4

A detailed analysis of discard rates for blood components by province is presented below. (*Please see commentary beneath the following table for an explanation of the methodology used to arrive at these estimates.)

Estimated Discard Rates for Products by Province

RED BLOOD CELLS	AB	BC	MB	NB	NF	NS	NT	ON	PE	SK	YT	Total
Total Shipped Units	94196	108384	39082	22883	17656	29204	733	368852	3174	33789	679	718632
Total # Hospitals	67	88	72	22	28	22	4	166	8	76	1	554
# Hospitals Participating	32	43	26	15	8	14	3	45	2	26	1	220
Hospitals as a %	48%	49%	36%	68%	29%	64%	75%	27%	25%	34%	100%	38%
Shipped Units as a %	45214	53108	14069	15560	5120	18691	550	99590	794	11488	679	264863
Hospital reported discarded units	2062	3928	1049	692	1339	834	192	1533	89	946	34	12698
Calculated Discard Rate %	4.6%	7.4%	7.5%	4.4%	26.2%	4.5%	35%	1.5%	11.2%	8.2%	5.0%	4.8%

PLATELETS												Total
Shipped	39682	51877	19242	11027	4940	12970	36	167402	727	12480	14	320397
Total # Hospitals	67	88	72	22	28	22	4	166	8	76	1	554
# Hospitals Participating	31	43	26	14	8	14	2	45	2	26	1	220
Hospitals as a %	46%	49%	36%	64%	29%	64%	50%	27%	25%	34%	100%	38%
Shipped Units as a %	18254	25420	6927	7057	1432	8300	18	45199	182	4243	14	117046
Hospital reported discarded units	3881	7594	0	1481	857	314	0	4286	0	2443	0	20856
Calculated Discard Rate %	21%	30%	0.0%	21%	60%	3.8%	0.0%	4.5%	0.0%	58%	0.0%	17.8%

CRYOPRECIPITATE												Total
Shipped	9017	5667	1327	493	771	1588	30	18725	23	1944	4	39589
Total # Hospitals	67	88	72	22	28	22	4	166	8	76	1	554
# Hospitals Participating	31	43	26	15	7	14	2	44	2	26	1	220
Hospitals as a %	46%	49%	36%	68%	25%	64%	50%	27%	25%	34%	100%	38%
Shipped Units as a %	4147	2777	478	335	192	1016	15	5056	6	661	4	14687
Hospital reported discarded units	232	420	69	68	60	43	0	478	29	30	8	1437
Calculated Discard Rate %	5.6%	15%	14.4%	20.3%	31%	4.2%	0.0%	9.4%	483%	4.5%	200.0%	9.8%

CRYOSUPERNATANT												Total
Shipped	6615	2592	1197	282	28	682	0	18250	0	715	0	30361
Total # Hospitals	67	88	72	22	28	22	4	166	8	76	1	554
# Hospitals Participating	20	17	13	13	7	12	2	43	1	16	1	145
Hospitals as a %	30%	19%	18%	68%	25%	55%	50%	26%	13%	21%	100%	26%
Shipped Units as a %	1985	492	215	192	7	375	0	4745	0	150	0	8161
Hospital reported discarded units	30	48	46	21	0	0	0	131	0	5	0	281
Calculated Discard Rate %	1.5%	9.8%	21.4%	11%	0.0%	0.0%	0.0%	2.8%	0.0%	3.3%	0%	3.4%

Note: The reader is cautioned that the annual volumes shipped by product to each individual province was collected from CBS historical data while the discard rate was collected from the individual hospitals participating in the survey and responding to specific questions within the survey. As a result a direct comparison or correlation of reported hospital discarded units to total units shipped to any individual province cannot be made.

To allow for some kind of comparison, we calculated an estimated discard rate as a percentage of total units shipped. We calculated the number of hospitals that provided their discard rates as a percentage of the total hospitals in the province. In respect of each product, the number of hospitals providing figures was then prorated against the total units shipped to each province.

The number of discarded units reported by hospitals was then looked at in comparison to the total number of shipped units (as a percentage of total units shipped to the individual province) in order to derive a calculated an "estimated" discard rate based on the information available.

This estimated discard rate incorporates several assumptions and should be used and interpreted cautiously. Assumptions assume that the hospitals sampled and participating are representative of the other hospitals in the province in size and blood product usage and discard rates. The estimated discard rate is a proxy variable indicating general trends only and should be interpreted with caution and requires further investigation and validation.

C. Performance Measurement

The survey looked at the performance of the current blood supply system in Canada. In particular, it asked respondents whether order lead times (from order placement to delivery) consistently meet their requirements; how often they receive their full order of Type "O" group blood, and how many elective surgeries requiring blood components are cancelled as a direct result of a blood product shortage. Respondents were generally satisfied with order lead times (83% reported that they consistently met their requirements), and reported receiving their full order of Type "O" group blood the majority of the time. The number of hospitals having to cancel elective surgeries because of blood product shortage was fairly low and appears to have decreased between 2000 and 2002.

Order Lead Times

Respondents were asked whether order lead times (from order placement to delivery) consistently meet their requirements. A total of 209 hospitals responded to this question and 83% of hospitals indicated that order lead times did meet their requirements. Of the 26 hospitals (12%) that indicated they did not, reasons cited included the following:

- Mix-ups by CBS, bus stations and/or taxi services
- Lateness of new drivers standing in for regular couriers
- Long distance from blood supply
- Transportation problems (not specified)
- Problems with after-hours and statutory holidays (not specified)
- Limited bus service to area
- Limitations imposed by flight departure times
- Order placement requirements (i.e., having to place orders by 11am)
- Unavailability of required product
- Changing needs of acute care
- Staffing levels
- Shipments transported by bus being lost

A detailed summary of order lead time satisfaction by province stratified by hospital size is presented below.

Province	Yes	Yes as a (%)	Hospital Size					No	Hospital Size				
			Small	**Medium**	**Large**	**Very Large**	**Don't Know**		**Small**	**Medium**	**Large**	**Very Large**	**Don't Know**
AB	27	82	20	4		1	2	4	4				
BC	38	88	22	11	2		3	4		1		3	
MB	22	81	18	3		1		4	3				1
NB	13	87	10	1		2		2	1			1	
NF	6	75	6					2	1			1	
NS	14	100	14					0					
NT	3	100	3					0					
ON	36	78	20	9	2		5	7	3	2	1		1
PE	1	50					1	1				1	
SK	23	85	21			1	1	1	1				
YT	0	0						1	1				
	218		**134**	**28**	**4**	**5**	**12**	**24**	**14**	**3**	**1**	**6**	**2**

Type "O" group blood

The majority of hospitals (64%) reported that on average they received their full order of Type "O" group blood (Rh+) 96 to 100% of the time. Thirteen percent received their full orders on average between 91 and 95% of the time, while only two percent reported receiving their full orders on average less than 80% of the time. A total of 188 hospitals responded to this question.

With respect to Type "O" group blood (Rh-), 34% of hospitals reported that on average they received their full order 96 to 100% of the time, while another 20% reported receiving their full order on average 90 to 95% of the time. Thirteen percent of hospitals reported receiving their full orders on average less than 80% of the time. A total of 182 hospitals responded to this question.

Cancellation of elective surgeries

Respondents were asked how many elective surgeries requiring blood components are cancelled annually as a direct result of a blood product shortage. Respondents provided meaningful data for analysis for the years 2000, 2001, 2002.

Number of elective surgeries cancelled out of 220 respondents

Year	NR	None	1-3	4-7	8-11	12+
Fiscal Year 2002 (April to June)	106	111	2	1	1	0
Fiscal Year 2001	117	91	5	5	4	0
Fiscal Year 2000	112	88	5	2	4	1

Fewer hospitals reported cancelling any elective surgeries in 2002 (two percent) than in 2001 (six percent) and 2000 (five percent). The response rate for years prior to 2000 is too low to extract any useful analysis. A marked improvement in the incidence of elective surgery cancellations due to blood component shortages is clearly seen when examined by the actual number of incidents by province. This information is summarized for the last three years in the table below.

Province	2002	2001	2000
BC	16	26	31
MB	0	1	1
NB	0	5	4
NF	0	0	1
ON	1	19	18
SK	0	10	30
	17	**60**	**84**

Reduction of platelet orders allocated to transfusion patients

Respondents were asked to indicate approximately how many platelet orders allocated to transfusion patients are reduced on an annual basis as a direct result of a blood component shortage. This information is displayed in the following table (205 Reponses).

Year	NR	None	1-3	4-7	8-11	12+
Fiscal Year 2002 (April to June)	111	95	6	4	3	2
Fiscal Year 2001	121	78	7	5	1	3
Fiscal Year 2000	129	73	11	1	1	2

The results indicate that the number of hospitals having to reduce platelet orders allocated to transfusion patients as a direct result of blood component shortages remained constant between 2000 and 2002, being seven percent for each of these fiscal years.

The annual reduction in platelet orders allocated to transfusion patients by province is presented below.

Province	2002	2001	2000
AB	8	8	8
BC	16	17	8
NB	1	8	7
NF	2	0	0
NS	0	0	2
ON	10	30	26
SK	35	111	127
	70	**172**	**176**

Unusable blood products

Ninety one percent of respondents indicated that less than one percent of blood products ordered are unusable due to improper processing, packaging or handling. Five percent of hospitals indicated that between one percent and five percent of blood products ordered are unusable. One hospital indicated an unusable percentage over five percent. A total of 213 hospitals responded to this question.

Mechanisms to deal with blood product quality issues

As to whether there is a clear mechanism in place to relay blood product quality issues to local Blood Centres, the majority (86%) of hospitals indicated that there was while only 12% indicated that there was not. A total of 217 hospitals responded to this question.

The majority of respondents indicated that they had no issues regarding how CBS is able to manage product quality related issues with the local blood centres. Results of the question "How would you best describe your local Blood Centre's ability to handle blood product quality issues?" are summarized in the following table.

Response	% of respondents
Action is swift and product quality follow-up occurs for a defined period	28%
Pro-active communication to ensure no product quality issues exist	23%
Other	14%
Records issue but action is slow	8%
Actions are taken initially but no follow-up	6%
No mechanism in place to handle	4%
Records issue but no noticeable action is taken	3%

Other comments made by the hospitals concerning the Blood Centres' ability to handle blood product quality issues included:

- Not sure if any mechanism in place
- Some respondents do not deal directly with CBS
- Some respondents had not experienced any blood product quality issues or not enough to answer the question

Fourteen percent of respondents did not answer or gave an ambiguous response.

Forty eight percent of respondents indicated that they had not had any meetings with representatives of their local Blood Centre over the past year. Forty three percent reported between one and three meetings. Only one percent reported 10 or more meetings. A total of 214 hospitals responded to this question. A detailed analysis of meetings with the local Blood Centre representative in the past year by province is presented below.

Province	Frequency of Meetings					
	No Mtgs	1 – 3	4 – 6	7 – 9	10+	Blank
AB	14	13	2		1	3
BC	19	18	4		1	1
MB	17	9			1	
NB	8	7				
NF	8					
NS	4	9				1
NT	3					
ON	11	27	7	1		
PE	1	1				
SK	15	10				1
YT	1					

Respondents were asked what type of support is provided by their local Blood Centres. Responses, in order of importance, were as follows:

Type of Support	Percentage
Information sessions on new and emerging products and research	32% (71)
Educational sessions on transfusion medicine	27% (59)
Educational sessions on utilization management	18% (39)
Written information (e.g., newsletter, literature etc)	12% (27)
Meetings	10% (21)
No support	8% (17)
Fax communication	8% (17)
Telephone communication	5% (12)
Memo's/Notices	5% (10)
Other	4% (8)
Customer updates (e.g., letters)	3% (6)
Symposiums/Seminars	2% (5)

A total of 192 hospitals responded to this question. Of those respondents who indicated that they did receive any of the types of support listed in the table above, the majority (62%) found the support to be useful. Nine percent were neutral, and only two percent found the overall effectiveness of the support to be poor. Seven percent did not know how they found the support's overall effectiveness.

A majority (41%) of respondents indicated that since September 1998, neither their local Blood Centre nor the CBS has ever contacted their hospital to get input on their level of satisfaction with the level of service they provide. However, a significant percentage (29%) indicated that they did not know. Fifty seven hospitals (26%) reported that either their local Blood Centre or the CBS has contacted them in this regard. A total of 211 hospitals supplied this information.

Of the 57 respondents that indicated they had been contacted, 42% indicated they had been contacted in 2002 while 35% had been contacted in 2001 and 2% had not been contacted since 1999. The remainder of respondents indicating they had been contacted did not provide a date. Summary results by province are presented on the following page.

	Local Blood Centre or CBS Contact with Hospitals Re: Customer Service Satisfaction						Small	Med	Large	Very Large	Don't Know Size
	Number of Hospitals	Yes	Yes (%)	No	DK	No response	<2,000	2,001 – 5000	5001 – 10,000	>10,000+	
AB	33	5	15%	14	12	2	11	1	1		1
BC	43	20	47%	11	10	2	9				1
MB	27	4	15%	12	9	2	7	3		1	1
NB	15	5	33%	7	3	0	6	1			
NF	8	0	0%	7	1	0	6			1	
NS	14	3	21%	8	2	1	8				
NT	3	1	33%	1	1	0	1				
ON	46	11	24%	18	15	2	8	5	1	1	3
PE	2	1	50%	1	0	0	1				
SK	27	7	41%	11	9	0	10			1	
YT	1	0	0%	0	1	0	N/A				

Note: The reader is cautioned that the local Blood Centre and / or CBS may have regular contact with the hospitals re: order placement and product management, but may not have or not perceived to have had discussions re: customer satisfaction and customer service levels provided to the individual hospitals.

D. Customer Satisfaction Assessment

In order to understand the type and magnitude of change the hospitals have experienced with the CBS as their supplier, a customer satisfaction assessment was incorporated in the survey. The purpose of this was to solicit an understanding of the perceptions and attitudes the hospitals held with regard to three dimensions of customer service, namely, timeliness, product quality, and customer service.

The respondents were asked to indicate on a Likert scale ranging from "very good" to "very poor" their opinion against specific statements related to the three customer service dimensions being measured. A total of 220 hospitals participated and the results are summarized below. The Likert Scale codes used in the table are as follows:

NR = No Response VG = Very Good G = Good N= Neutral P = Poor VP = Very Poor

Timeliness	**No Response (%)**	**VG (%)**	**G (%)**	**N (%)**	**P (%)**	**VP (%)**
Responds in a timely manner on CBS related enquiries	2	40	**48**	6	2	1
Provides products in a timely manner	3	**45**	**45**	4	1	1
Is time sensitive with minimal delays in processing orders	3	**47**	43	7	1	0
Provides appropriate information and status of orders in a timely manner	3	**41**	41	11	5	1

When asked "How has **timeliness** changed since 1998?", the majority (64%) of respondents indicated that there had been no change. Twenty seven percent indicated that there had been an improvement, while only six percent reported that the situation had worsened. A total of 213 hospitals responded to this question.

Product Quality	**NR (%)**	**VG (%)**	**G (%)**	**N (%)**	**P (%)**	**VP (%)**
Continuously monitors process to ensure integrity of components	7	41	**45**	5	1	1
Identifies opportunities for improvement	9	26	**45**	19	1	1
Is effective in fulfilling current mandate	11	30	**46**	14	0	0

When asked "How has **quality** changed since 1998?", thirty five percent of respondents felt that product quality had improved since 1998, while the majority

(55%) felt that there had been no change. Only one percent of respondents felt that quality had worsened. A total of 201 respondents answered this question.

The lowest level of customer satisfaction indicated by respondents was to the statement "Identifies opportunities for improvement." Only 45% responded "good" and 26% as "very good" for a combined 71% response rate in the positive compared to other statements averaging 80% or above."

Customer Service	**NR (%)**	**VG (%)**	**G (%)**	**N (%)**	**P (%)**	**VP (%)**
Local Blood Centre is a valuable resource	5	**43**	37	12	2	1
Has a structured and effective order management process	4	38	**45**	12	1	1
Is able to consistently deliver "full orders" of blood components on time	4	33	**47**	12	5	0
Is responsive to customer needs and therefore is a good "supplier"	4	**45**	39	10	3	1
Works to ensure customer requirements are consistently met	4	42	**44**	9	2	0

When asked "How has **service** changed since 1998?", a majority (60%) of respondents indicated that service had not changed since 1998. Thirty four percent said that services had improved, while only two percent said that services had worsened. A total of 211 respondents answered this question.

Customer Identified Opportunities for Improvement

Respondents were asked what changes they would like to see to improve customer service and efficiency in the CBS supply chain. For the purposes of analysis, the major suggestions for improvement were divided into categories. The responses are summarized according to these categories in the following table:

Changes	**Percentage of respondents**
No response	45% (100)
No change/satisfied	14% (31)
Better/improved transport services (e.g., bus, courier)	13% (28)
Better administrative communication (including notifying shortages)	11% (24)
Other	6% (14)
More educational sessions	7% (16)
Better access to the CBS (i.e., distance, location)	5% (10)

Changes	Percentage of respondents
Less paperwork	3% (6)
Need more donations	3% (7)
Provide name of contact person	1% (3)
Better verbal communication skills	2% (4)
Computerize the system	3% (6)

Below, we look in more detail at the suggestions made for improvement.

Better / improved transport services

A commonly recurring theme was the **need to improve transport of products** to be more efficient, reliable, and flexible. In short, respondents wanted:

- To reduce their dependency on third party carriers
- Enhanced timeliness of delivery of product
- Enhanced tracking of order status
- Standardized packaging for shipping across Canada

Better administrative communication

Respondents wanted "*better communication*", including:

- Confirmation for each order placed (e.g., as one hospital noted, "*we would like a quicker fax back reply to orders that are placed. Order confirmations are often not received by the time the day staff is gone (1600hr). Sometimes we wonder if the order got through [and] sometimes we call to confirm and that's a waste of everyone's time!*")

- Advice re availability of products (e.g., one respondent noted that due to bad communication, they had been unaware for several years that a particular fractionated product was available)

- Enhanced customer service (e.g., one hospital wanted more meetings with their local Blood Centre; another wanted to see better communication amongst CBS staff so all questions asked receive the same consistent and accurate answers; another reported that "*When we ask questions I would like an answer – they never get back to me.*")

- Enhanced communications on supply chain issues re inventory and product availability, product handling, and changes in delivery methods

Notification of shortages / delivery time etc.

Hospitals wanted to see:

- Notification of inventory levels on hand at the CBS
- Proactive notification of blood shortages: as described by one hospital:

> "*patient safety is jeopardized when we are not notified promptly. We should not have to argue, beg and plead for product. Our wastage level is very low. We need it! CBS have little or no understanding of hospital/patient issues – we are unable to predict when emergencies will occur. Some CBS staff on call after-hours make it clear that they are not happy to be called out to issue product. NO sense of patient requirements.*"

- Advanced shipping notice for product – date / time / method of delivery – air or ground

Education/Support

There were a number of suggestions that CBS service would be improved by "increased and/or more effective education". In summary, respondents wanted:

- Education that is targeted to institution and product user population – size and product use
- Product information being distributed should be relevant (e.g., one respondent said that they get a lot of information memos on products they have never heard of and have no idea who needs this information. Another hospital with a similar complaint recognized the need to inform but found information provided to be irrelevant to a small rural hospital.)
- After-hours support
- Availability of administrative policies / procedures re blood products for internal use by the institution (e.g., how long to keep paperwork, how it should be filed etc.)

Distance

A number of hospitals in rural areas (e.g., in Newfoundland, New Brunswick, Alberta, Manitoba) reported that **distance is a problem in terms of effective and reliable delivery times**. Comments made included the following:

- One hospital in Alberta said that their problems all lie in the transportation from CBS to their facility, with only one bus per day from Edmonton and one bus going to Edmonton. One hospital in Manitoba noted that for urgent needs, "*family members have driven to pick up the required blood*".

- Some hospitals emphasized that distance means it is difficult to get product on time in emergencies (e.g., in Newfoundland and Nova Scotia). One hospital in Newfoundland said that as such they cannot afford to let supply drop to emergency levels.

- Distance was not always reported as being a problem, for example, one hospital in New Brunswick said that "*given the distance that exists between our hospital and CBS, I think we receive excellent service. With our inter-regional network, we have also kept product expiration at an all time low. I am pleased with the service and can not think of any changes that may improve services.*" Similarly, one hospital in northern Manitoba said "*I believe it is as good as it can be considering where we are geographically*".

- At least three hospitals in Saskatchewan were concerned about the upcoming closure of the CBS site in Saskatoon, as this would mean they would be a long distance from the nearest centre in Regina.

Less paperwork

Key points made by respondents were that:

- The required "special access approval" for certain products is too cumbersome and difficult for hospitals to manage and needs to be streamlined.

- An electronic means of ordering blood products would be desirable.

Need more donations

Key suggestions concerning improvement in the area of donations were:

- That there are not enough donors.

- That phone outs for donations be done by more knowledgeable people who have some medical background.

- Access to donor information would be useful for the purposes of traceback/lookbacks, phenetyping etc.

- One hospital wanted to see an Autologous Donation Service at the local permanent CBS clinic as well as 24/7 antibody identification.

Provide name of contact person

Respondents suggested:

- A directory of who to contact if problems occur
- That Blood Centres should designate a specific hospital liaison person / customer service co-ordinator who is familiar with each that hospital's operation.

Better communication skills

- A key point was that CBS staff answering telephones need to have good communication skills and a clear understanding and grasp of the English language.

Computerization

- Some respondents wanted to see a computerized system linking all hospitals with CBS so that product inventories can be identified and moved more efficiently

Other

Other suggestions included:

- A standardized format for blood component requests
- The facility to leave an order for products "after hours" rather than phoning the technician "on call"
- A system of automatic substitution of products when stock is low
- One hospital said that previously they were able to rotate stock every two weeks to avoid outdating and return units to CRC to be issued to high volume users. They would like to see this system implemented again because of outdating issues that occur in small volume hospital sites. On the same theme, another hospital wanted to see a better mechanism to return older units from remote rural locations so they can be used before they are outdated.
- One hospital reported needing a better mechanism to deal with problems and noted that they have had frequent breakages of AFFP bags with no resolution as yet.
- Regarding customer service, one hospital said: "*we would like to see CBS recognize that they are a service organization and that their customers are the hospitals. As such they should determine the needs of their customers and*

respond appropriately rather than rely on the response that "our regulations will not allow us to do that"."

- Concerning management of CBS, one hospital said that "*overall the service is good. I would, however, prefer to see Blood Transfusion/Hematology specialist in the Medical Director's position. Some clinical decisions are made mainly on cost of product rather than on the need of the patient. I wonder if this might be different if the expertise of the Medical Director was Hem/BB rather than anaesthesiology.*"

- A better mechanism to deal with platelet requests. One hospital suggested that the turn around times for NAT needed to be improved so that platelets are available sooner. Another suggestion regarding platelets came from a hospital that wanted to change the days of collection or number of days for collection. This hospital said that a three day collection break causes problems in supplying platelets that have a five day expiry date.

- It was recognized by one hospital that problems with product supply are not always CBS's fault: "*often with fractionated products it's the supplying company that cannot meet demand therefore limiting our supply e.g., for a 0.5 vial of HBIG we are issuing 5ml. Also, factor VIII is cut back to half orders resulting in more frequent ordering, more work for us and CBS to process orders.*"

- A better system organized for small hospitals to send in samples for antibody investigations and antibody investigation turnaround times improved.

- A general suggestion was made by one hospital that CBS needed a better understanding of hospital issues.

- That CBS consult with users as to the placement of labels on fresh products ("*e.g., computer generated label used by hospital has to be placed over part of the blood label and if computer label has to be removed it tears off some of the original label at the same time*".)

- With respect to the EDR process, one hospital suggested there needs to be a complete rework of the process.

- Access to donor information would be useful for the purposes of traceback/ lookbacks, phenetyping etc

APPENDIX G

Suggested Template:
Canadian Blood Services Three Year Corporate Plan

CONTENTS

1. Review of Financial Performance for the Previous Year
2. Proposed Budget for Upcoming Year (Year 1)
3. Financial Forecasts for Years 2 and 3
4. Results for Key Performance Indicators
5. Transformation Project Update
6. Three Year Service Plan

Appendices
Glossary of Terms and Acronyms
Definition of Budget Categories
Audited Financial Statements

Part I
Review of Financial Performance for the Previous Year

- CBS Past Performance Budget Review
- Centre Past Performance Review (Financial Performance relative to budget; financial performance relative to previous year's actual; trends in whole blood collections)
- Highlights of CBS Achievements

CBS Past Performance Budget Review

Period:

		FTE's	Cost of Goods Sold	Staff Costs	Medical Supplies	Clinic Costs	Travel	Admin. Services	Profess. fees	Other services	Property Expense	Equip.	Misc. Expense (Income)	Royalty	Total	Reason for Variance
Blood Operations																
Blood/Plasma Centres	Actual Budget Variance % Chg Var															
Field Support	Actual Budget Variance % Chg Var															
Corporate Services (Head Office)	Actual Budget Variance % Chg Var															
R&D	Actual Budget Variance % Chg Var															
Projects (CBS Funded)	Actual Budget Variance % Chg Var															
Total Blood Operations																
	Actual Budget Variance % Chg Var															
Fractionation																
	Actual Budget Variance % Chg Var															
Patient Services																
	Actual Budget Variance % Chg Var															
UBMDR																
	Actual Budget Variance % Chg Var															

CONSOLIDATED TOTAL																
	Actual															
	Budget															
	Variance															
	% Chg Var															

Centre Past Performance Overview

Period:

	B.C. & Yukon	Calgary	Edmonton	Regina	Sask.	Winnipeg	Sudbury	Londom	Hamilton	Toronto	Ottawa	Saint John (NB)	Halifax	P.E.I	Nfld.	National Laboratories	Thunder Bay Plasma Centre	PEI Plasma Centre	Total	Comments
Financial Performance																				
Actual $ - Current Year																				
Budget $																				
Variance $																				
% Variance																				
Actual $ - Previous Year																				
Variance $ – Previous Year vs Current Year																				
% Variance – Previous Year vs Current Year																				
Whole Blood Collections																				
W.B. Collections – Actual Units Current Year																				
W.B. Collections – Budgeted Units Current Year																				
W.B. Collections – Variance Units																				
W.B. Collections - % Variance Units																				
W.B. Collections – Actual Units – Previous Year																				
W.B. Collections – Variance Units – Previous Year vs Current Year																				
W.B. Collections - % Variance – Previous Year vs Current Year																				

Highlights of CBS Achievements Over the Past Year

Part 2
Proposed Budget for the Upcoming Year (Year 1)

- CBS Proposed Budget by Major Cost Division
- CBS Proposed Budget (FTEs and Dollars) by Functional Area**
- Provincial Budget Allocations

**Reporting expenditures by functional area is a departure from how CBS currently reports financial information to the Members. Assigning costs to functions provides a better understanding of what funds will be used for. It is suggested that reporting of functional area information be piloted for the next budget cycle and assessed.

CBS Proposed Budget for Year 1

Period:

	FTEs	Cost of Goods Sold	Staff Costs	Medical Supplies	Clinic Costs	Travel	Admin. Services	Professional Fees	Other services	Property Expense	Equip.	Misc. Expense (Income)	Royalty	Total	Assumptions
Blood Operations															
Blood Plasma Centres															
Field Support															
Corporate Services (Head Office)															
R&D															
Projects (CBS Funded)															
Total Blood Operations															
Fractionation															
Patient Services															
UBMDR															
CONSOLIDATED TOTAL															

Budget by Functional Area and FTE Allocation For Year 1

Period:

	FTEs	Budget $
Blood Operation Costs		
Donor Recruitment		
Blood Collections – Whole Blood		
Blood Collections – Plasma via Plasmapheresis		
Blood Collections – Platelets via Cytapheresis		
Manufacturing/Processing		
Donor Blood Testing		
Storage and Distribution		
Quality Assurance and Quality Control		
Administration/Overhead – National Level		
Administration/Overhead – All Regional Blood Centres		
Research & Development		
Other Blood Operations		
Total Blood Operations		
Fractionation		
Fractionated Product		
Fractionated Product Overhead/Administration		
Total Fractionation		
Patient Services		
Patient Services Direct Service		
Patient Services Overhead/Administration		
Total Patient Services		
UBMDR		
UBMDR Direct Service		
UBMDR Overhead/Administration		
Total UBMDR		
CONSOLIDATED TOTAL		

Provincial Budget Allocations

Period:

	Blood Operations				Fractionation		Patient Services		UBMDR		CBSI	
Province / Territory	**Previous Year Actual RBC Units Shipped**	**Previous Year Actual RBC Costs**	**Budget $**	**Previous Year Actual Costs**	**Budget $**	**Previous Year Actual Costs**	**Budget $**	**Previous Year Actual Cost**	**Budget $**	**Winnipeg Building**	**Captive Insurance**	**Total**
British Columbia												
Alberta												
Saskatchewan												
Manitoba												
Ontario												
Quebec												
Newfoundland												
P.E.I.												
New Brunswick												
Nova Scotia												
Yukon												
Northwest Territories												
Nunavut TOTAL												

The budget would be based on the volume of blood components, fractionated products and patient services that each jurisdiction is expected to utilize in the coming year.

Part 3
Financial Forecasts for Year 2 and Year 3

- Financial Forecast Year 2
- Financial Forecast Year 3
- Summary: Historical Performance and Forecasts

CBS Forecast for Year 2

Period:

	FTEs	Cost of Goods Sold	Staff Costs	Medical Supplies	Clinic Costs	Travel	Admin. Services	Professional Fees	Other services	Property Expense	Equip.	Misc. Expense (Income)	Royalty	Total	Assumptions
Blood Operations															
Blood Plasma Centres															
Field Support															
Corporate Services (Head Office)															
R&D															
Projects (CBS Funded)															
Total Blood Operation Costs															
Fractionation															
Patient Services															
UBMDR															
CONSOLIDATED TOTAL															

CBS Proposed Forecast for Year 3

Period:

	FTEs	Cost of Goods Sold	Staff Costs	Medical Supplies	Clinic Costs	Travel	Admin. Services	Professional Fees	Other services	Property Expense	Equip.	Misc. Expense (Income)	Royalty	Total	Assumptions
Blood Operations															
Blood Plasma Centres															
Field Support															
Corporate Services (Head Office)															
R&D															
Projects (CBS Funded)															
Total Blood Operation Costs															
Fractionation															
Patient Services															
UBMDR															
CONSOLIDATED TOTAL															

Summary: Historical Financial Performance and Forecasts

Period:

	Actual				**Current Budget**	**Forecasts**			
	1998/1999	1999/2000	2000/2001	2001/2002	2002/2003	2003/2004	2004/2005	2005/2006	Assumptions
Blood Operations									
Fractionation									
Patient Services									
UBMDR									
CONSOLIDATED TOTAL									

Part 4
Key Performance Indicators

- Results for Key Performance Indicators

*Note: The key performance indicators to be reported should be based on the Members needs for information to support decision-making and address accountability requirement
Several performance indicators have been proposed in this suggested template but the final decision should be based on discussion between CBS and the Members. Also, some o
the indicators included in the template are not currently collected (e.g. hospital data on elective surgery cancellations) however, they are included because of the potentially important information they can provide on the adequacy of the blood system. Some of the indicators will require collaboration with hospitals (including an education component) and will have to be phased in over time.

Results for Key Performance Indicators

Indicator	Target	Previous Year Actual	Current Year Actual	Comments and Explanation of Variances
Number of Active Donors				
% of Eligible Population that are Active Donors	5%			
Collections – Whole blood				
Collections – Platelet apheresis				
Collections – Plasmapheresis				
Volume of plasma shipped for fractionation				
Cost per unit – Red blood cells				
Cost per unit – Apheresis platelets				
Cost per unit – Recovered platelets				
Cost per unit – Apheresis/source plasma				
Cost per unit – Recovered plasma				
Labour hours per unit of red blood cells				
% of hospital orders shipped	100%			
Number of elective surgery cancellations due to blood product shortages	0			
Incidence of adverse transfusion events related to CBS activities				
Number of deaths due to adverse blood reactions	0			
Centre discard rate - Red blood cells				
Centre discard rate - LRF Platelets				
Centre discard rate - Apheresis Platelets				
Number of repeat Audit Observations				
Staff Turnover Rate				
Number of employee grievances				
Average attendance rate at Board meetings				

Part 5
Transformation Project Update

- Status Report for Projects In Progress
- Status Report for Projects without completed business cases

Status Report for Projects in Progress

Note: Business Cases should be available to Members and P/T Contacts upon request.

Project Name	**Project Description**	**Implementation Start Date**	**Expected Implementation End Date**	**Project Status Relative to Project Budget (at/under/over budget and reasons)**	**Project Status Relative to Project Timelines (ahead/ behind/on schedule and reasons)**	**Project Status Relative to Human Resource Plan**	**Project Performance Metrics and Results**	**Project Issues (project changes, labour issues, safety issues, cost issues, risk issues, etc.)**

Status Report for Projects without Completed Business Cases

Project Name	**Brief Project Description**	**Expected Date for Completion of Business Case**	**Expected Implementation Timeframe**	**Implications of Project Implementation (e.g. financial, staffing, etc.)**

Part 6
Three-Year Service Plan

This component of the submission would be a narrative document. Content would include:

- Organizational Overview
    - About CBS
    - List of Board Members
    - Corporate Organizational Chart
    - Staffing
    - Brief Description of Service Delivery Model
    - Key activity metrics

- Three Year Plan describing Proposed Changes to:
    - Blood Operations
    - Fractionated Products
    - Patient Services
    - Unrelated Bone Marrow Donor Registry
    - Cost-Benefit-Risk Assessments to Support Significant Changes
    - Financial Investment/Savings Plan (if required)
    - Capital Plan (if required)

APPENDIX H: GLOSSARY OF ACRONYMS USED IN THIS REPORT

AABB
American Association of Blood Banks

International organization of blood banks, transfusion services, and individuals engaged in blood banking and transfusion standards determination. Standards do not carry force of law.

ABO
Blood Group Types (can be A, O ,B, or AB)

The blood group of an individual is dependant on the presence or absence of proteins and sugars called antigens on the surface of blood cells as well as the proteins called antibodies in the watery part of the blood.

There are four major blood groups: A, O, B, and AB divided into Rh Positive and Rh Negative types. The most common type in Canada is O Rh Positive. People with O Rh Negative blood are considered universal blood donors because patients of all blood types can receive O Rh Negative blood.

ADMS
Alarm/Data Monitoring System

Computer software system used to monitor ambient conditions in manufacturing environment (e.g. fridges and freezers, areas where medical supply inventories are used or stored).

AFFP
Apheresis Fresh Frozen Plasma

Apheresis Fresh Frozen Plasma is collected by apheresis and frozen within eight hours. Trisodium Citrate anticoagulant is added during the apheresis process. Apheresis Fresh Frozen Plasma contains plasma proteins including all coagulation factors. Apheresis Fresh Frozen Plasma is indicated for massive transfusion (replacement of patient's blood volume in less than 24 hours) with demonstrated deficiency of Factor VIII and V, otherwise Plasma is adequate. Apheresis Fresh Frozen Plasma is also indicated in exchange transfusion in neonates.

Anti-HBc
Antibody to Hepatitis B Core

A test for Hepatitis B that detects the presence of circulating antibodies made by the host in response to the Hepatitis B "core" antigen. At this time, this test is not performed by CBS though discussions are underway with Health Canada regarding the core test. Core testing is being performed in the United States. CBS currently tests for Hepatitis B using the HBsAg (Hepatitis B Surface Antigen) test that detects the outer envelope of the Hepatitis B virus.

BCIS
Blood Component Issuing System

Computer system used to distribute blood components from blood centres to hospitals.

BERD
Blood Establishment Regulatory Division

The division of Health Canada that regulates Canada's blood supply system.

BERG
Blood Education Resource Group

Group commissioned by CBS that was tasked to review the current availability of educational resources and identify the needs for specific additional resources for physicians, technologists, nurses, patients/families, and public at large.

BLIS/BLIS 2000
Blood Information System

Computer software system used to manage the CBS donor base and donation information. BLIS 2000 is the year 2000 revision (i.e. Y2K compliant) of the former BLIS program. To be replaced by the MAK system.

CBA
Canadian Blood Agency

Formed in 1991 as a federal, not for profit corporation through which the provinces and territories would fund and direct the blood system.

CBC
Canadian Blood Committee

During the 1980s, the CBC administered provincial and territorial funding for the Red Cross.

CBS
Canadian Blood Services

A not-for-profit charitable organization whose mandate is to manage the blood supply in all provinces and territories (excluding Quebec).

CBSI
Canadian Blood Services Insurance, Inc.

The wholly owned subsidiary of CBS, and captive insurance company, which provides comprehensive insurance coverage for all blood related liabilities.

CEO
Chief Executive Officer

The most senior manager in an organization.

CFO
Chief Financial Officer

The most senior manager in an organization with responsibility for the finance function.

cGMP/GMP
Current Good Manufacturing Practices/Good Manufacturing Practices

Regulations that prescribe the materials, personnel, methods, equipment, facilities, and controls required for the safe and effective production of human and veterinary products, medical devices, and processed food. They define a quality system that manufacturers must use as they build quality in to their products. For example, approved blood products and components developed and produced according to GMPs are deemed to be effective, safe, properly identified, of the correct strength, pure, of high quality, and suitably labeled.

Good Manufacturing Practices is the terminology used in Canada, while Current Good Manufacturing Practices is the terminology used in the United States.

CIHI
Canadian Institute for Health Information

CIHI is the national, not-for-profit organization responsible for coordinating the development and maintenance of Canadian integrated health information system. Created in 1996 by Canada's Health Ministers.

CIHR
Canadian Institutes of Health Research

Canada's major federal funding agency for health research. Its objective is to excel, according to internationally accepted standards of scientific excellence, in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system. Formerly known as the Medical Research Council.

CIO
Chief Information Officer

The most senior person in an organization with responsibility for information management and information technology.

CJD
Creutzfeldt Jakob Disease

Known as Classical CJD, a neurodegenerative disease with sporadic occurrence in people with a mean age of 60 and incidence rate of one-in-one million worldwide for which there is no evidence of transmissibility through blood. Variant Creutzfeldt Jakob Disease (vCJD) differs from CJD and represents theoretical risk of being transmissible through blood. Also see vCJD.

CMV
Cytomegalovirus

Virus related to the herpes virus that can be transmitted through blood. In immune competent individuals, causes flu like symptoms while it can cause potentially fatal disease in immuno-compromised patients. CBS tests a portion of blood donations for CMV to be able to provide hospitals with a supply of CMV negative blood. Risk of transmission greatly reduced by leukoreduction.

COP
Centre Operating Procedure

A Centre specific work instruction for manufacturing related process.

CPM
Clinic Performance Monitoring

A tool to monitor performance of blood donor clinics by measuring labour hours expended at clinics against the clinic's output; and cost per unit.

CRCS
Canadian Red Cross Society

Charitable organization and former operator of the blood supply system.

CRM
Customer Relationship Management

CRM is a business strategy the outcomes of which optimize profitability, revenue and customer satisfaction by organizing around customer segments, fostering customer-satisfying behaviors and implementing customer-centric processes. CRM technologies should enable greater customer insight, increased customer access, more effective customer interactions, and integration throughout all customer channels and back-office enterprise functions. (Source: The Gartner Group)

CUE
Confidential Unit Exclusion

Process by which an individual donor notifies CBS in confidence at time of donation that his/her unit is/is not to be used for transfusion.

DOP
Departmental Operating Procedure

Department (usually Head Office) specific work instruction.

EMT
Executive Management Team

The CBS Senior Management Team comprised of the Chief Executive Officer; Executive Vice-President, Medical, Scientific and Clinical Management; Executive Vice-President, Operations; Executive Vice-President, Safety and Performance Management; Vice-President, Human Resources and Organizational Development; Vice-President, Corporate Services & Chief Financial Officer; Vice-President and General Counsel; Director, Corporate Planning and Executive Assistant to the Chief Executive Officer.

ESS
Event Scheduling System

Automated system for the scheduling and planning of blood donor clinics as well as staff scheduling for blood donor clinics.

FFP
Fresh Frozen Plasma

Fresh Frozen Plasma is separated from Whole blood, and frozen within eight hours of collection. Fresh Frozen Plasma contains proteins including all clotting factors. Plasma also has volume expansion properties. Fresh Frozen Plasma is indicated for massive transfusion (replacement of patient's blood volume in less than 24 hours) with demonstrated deficiency of Factor VIII and V, otherwise plasma is adequate for transfusion.

FDA
Food and Drug Administration

Agency of the United States' Department of Health and Human Services that regulates blood and blood products.

FPMS
Fractionated Products Management System

The computer system used by CBS to manage the inventory and distribution of fractionated products.

F/P/T
Federal/Provincial/Territorial

Federal, Provincial and Territorial Governments.

FTE's
Full-Time Equivalents

Staffing measure expressed as the number of full-time staff where full-time is defined as 1,950 working hours per year.

GMP/cGMP
Good Manufacturing Practices/Current Good Manufacturing Practices

Regulations that prescribe the materials, methods, equipment, facilities, and controls required for the safe and effective production of human and veterinary products, medical devices, and processed food. They define a quality system that manufacturers must use as they build quality into their products. For example, approved blood products and components developed and produced according to GMPs are deemed to be effective, safe, properly identified, of the correct strength, pure, of high quality, and suitably labeled.

Good Manufacturing Practices is the terminology used in Canada, while Current Good Manufacturing Practices is the terminology used in the United States.

HBV
Hepatitis B Virus

The virus that causes Hepatitis B. CBS currently tests for Hepatitis B using the HBsAg (Hepatitis B Surface Antigen) test that detects the outer envelope of the Hepatitis B virus.

HCV
Hepatitis C Virus

The virus that causes Hepatitis C. CBS performs an antibody test for Hepatitis C that detects antibodies to the Hepatitis C virus which are developed by the host in response to the presence of the virus. CBS also performs NAT testing for HCV which is a test that directly tests for genetic material of the virus itself.

HIV-1/HIV-2
Human Immunodeficiency Viruses 1 and 2

The viruses that cause AIDS (Acquired Immune Deficiency Syndrome). CBS performs an antibody test for the HIV-1 and HIV-2 viruses that detects antibodies to these viruses. CBS also performs an antigen test (HIV-1 p24) for the HIV-1 antigen and performs NAT (Nucleic Acid Amplification Testing) that tests directly for the genetic material of the HIV-1 virus.

H.Q.
Hema-Quebec

The agency responsible for the blood program in the province of Quebec.

HTLV – I/II
Human T-Cell Lymphotropic I and II Viruses

Viruses that can cause a rare form of leukemia in adults. Transmission in blood greatly reduced by leukoreduction. CBS uses a test to detect antibodies to HTLV – I and II viruses which are produced by the host in response to the presence of the virus.

HVAC
Heating, Ventilation, Air Conditioning System

Heating, ventilation, air conditioning systems, or those facility systems which are among the manufacturing critical systems and therefore require system validation.

IGIV/IVIG
Intravenous Immune Globulin

Proteins (antibodies) extracted from human plasma that are primarily used to treat patients with immune disorders, either immune (antibody) deficiency disorders or autoimmune disorders.

NB: Acronyms are used interchangeably.

Components of the validation process in which:

ISO
International Organization for Standardization

Global federation of national standards bodies from some 130 countries that work towards creating consistent international quality standards.

IS/IT
Information Services/Information Technology

Acronyms and terms used interchangeably.

IVIG/IGIV
Intravenous Immune Globulin

Proteins (antibodies) extracted from human plasma that are primarily used to treat patients with immune disorders, either immune (antibody) deficiency disorders or autoimmune disorders.

NB: Acronyms are used interchangeably.

LB/TB
Lookback/Traceback

Lookback begins with a donor who has tested positive for a transmissible disease. CBS conducts a targeted search to identify the patients who may have received earlier donations from that donor, to have these recipients tested for the infection in question.

Traceback begins with a patient who may have a transfusion-related infection. CBS conducts a targeted search to identify the donors who gave that person blood and who may have been the cause of the infection.

LHU
Labour Hours Per Unit

Performance indicator that measures labour hours expended per unit of whole blood collected.
LIS
Laboratory Information System

Computer system used to integrate donor testing results from testing equipment with appropriate donor and clinic data in BLIS 2000 (Blood Information System). Also referred to as LDMS (Laboratory Data Management System).

LRF
Leukocytes reduced by filtration

A filtration process to remove white blood cells from whole blood.

MAK
MAK System

Vendors of the "Progesa" software that will be used by CBS to manage blood collection, processing and distribution to hospitals. It will replace existing systems such as BLIS 2000 (Blood Information System) and BCIS (Blood Component Issuing System). MAK also handles "Traceline" software that manages the tracking of blood from hospital blood banks to recipient.

MOU
Memorandum of Understanding

Usually refers to the document signed in 1997 by the Federal/Provincial/Territorial Ministers of Health to establish a "National Blood Authority", later to be named Canadian Blood Services.

NAT
Nucleic Acid Amplification Testing

A new screening test for Hepatitis C and HIV relying on the detection of viral genetic materials, rather than the host's immune response to the infection. CBS has implemented NAT testing for both viruses. NAT is not a Health Canada licensed test (unlike other testing performed by CBS) but is being undertaken as an investigational new drug test.

NBSC
National Blood Safety Council

Council responsible for providing advice to the Minister of Health on public health, ethical, public policy, and other issues pertaining to blood safety, within the responsibility of the Federal government.

NLC
National Liaison Committee

A one-year pilot, consisting of two meetings, started on October 22, 2001. The NLC is co-chaired by the two CBS Board of Director's Consumer Representatives and is comprised of CLC delegates, representatives from national organizations such as consumer groups, patient/recipient groups, health care professionals, hospitals, and national sponsors. Created in response to the recommendations of the public participation task force.

NTL
National Testing Laboratory

Head Office Laboratory which provides testing support to blood centres; performs confirmatory transmissible disease testing for all blood centres; and houses one of CBS' four NAT laboratories.

OH&S
Occupational Health and Safety

A division of Human Resources and Organizational Development that is responsible for the management of Canadian Blood Services' Health and Safety System and Disability Management Programs.

p24
HIV-1 p24 Antigen

A test used by CBS to test for the HIV-1 virus. The test screens for antigens of the HIV-1 virus. CBS also performs an antibody test for the HIV-1 and HIV-2 viruses that detects antibodies to these viruses and performs NAT (Nucleic Acid Amplification Testing) that tests directly for the genetic material of the HIV-1 virus.

PBCO
Provincial Blood Coordinating Office

An office of the British Columbia Ministry of Health Services established to integrate and coordinate management of the provincial blood system including inter-hospital transfer of blood and blood products.

PDSI
Principle Decision Systems International

Automated system used for the scheduling of blood donors.

PO/PMO
Project Office/Project Management Office

The department within CBS that coordinates projects within the organization and advocates best practices in project management.

P/T
Provincial/Territorial

Provincial and Territorial Governments

QC
Quality Control

Testing of random samples of blood products manufactured by CBS; other products manufactured by CBS (e.g. HLA test kits); and medical supply inventories used by CBS (e.g. blood bags), to ensure that they meet pre-defined quality standards.

QIR
Quality Improvement Report

Alternative term for NCR (Non-Conformance Report) which is a report that provides details on a deviation from a manufacturing process including description, contributing factors, root cause analysis, corrective action, and measures to minimize potential for recurrence. Depending on the nature of the non-conformance, reporting to the BGTD (Biologics and Genetic Therapies Directorate) might be required.

QSA
Quality Systems Associate

CBS, professionally trained quality systems personnel who are responsible for performing: a quality assurance overview of manufacturing processes; internal audits; incoming supplies and materials qualifications; document and data control; change control; non-conformance management; and training and competency evaluation.

QSM
Quality System Manager

CBS, professionally trained quality systems management personnel who are responsible for ensuring: a quality assurance overview of manufacturing processes; internal audits; incoming supplies and materials qualifications; documents and data control; change control; non-conformance management; and training and competency evaluation.

RBC
Red Blood Cell

Red Blood Cells are the cellular component of whole blood that carry oxygen (bound to hemoglobin) to the tissues.

Red Blood Cells are the primary product manufactured by CBS from a whole blood donation.

RFP
Request for Proposal

Request for Proposal is a formal tender document used for purchases over $30,000 and does not meet the criteria of an RFQ.

RP
Recovered Plasma

Recovered plasma is the plasma that is removed from a whole blood unit during the processing of packed red cells (+/- platelet concentrate). It is differentiated from Source Plasma, which is plasma collected from the donor as an isolated product using a plasmapheresis procedure in which the cells are returned to the donor and only the plasma is donated.

S&PM
Safety and Performance Management

Division within Canadian Blood Services responsible for maximizing the quality and safety of CBS' manufacturing related processes and subsequent products.

SAP
Systems Applications and Products

Off-the-shelf computer software used by CBS to manage financial transactions.

SIRP
Service Interruption Recovery Plan

Emergency, contingency plans to guide operations during times of service interruption (e.g. power failure, major snow storm, etc).

SOP
Standard Operating Procedure

System wide work instruction for a manufacturing related process.

TB/LB
Traceback/Lookback

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Traceback begins with a patient who may have a transfusion-related infection. CBS conducts a targeted search to identify the donors who gave that person blood and who may have been the cause of the infection.

TD
Transmissible Disease

Disease that can be transmitted from one person to another.

UBMDR
Unrelated Bone Marrow Donor Registry

The function within CBS that locates compatible, committed, healthy unrelated donors for Canadian bone marrow transplant patients and for patients around the world.

UK
United Kingdom

US
United States

vCJD
Variant Creutzfeldt-Jakob Disease

A neurodegenerative disease that occurs in people thought to be caused by exposure to contaminated beef products from cattle with BSE. To date, cases have only been diagnosed in the United Kingdom (>100) and France (3). The human equivalent of "mad-cow" disease.

WB
Whole Blood

The unit collected directly from a donor before separation into components. Comprised of red blood cells; white blood cells; platelets; and plasma.

WBC
White Blood Cell

Cellular component of the blood that is responsible for protecting the body from invasion by foreign substances such as bacteria, fungi, and viruses.

Acknowledgement: Many of the definitions above were provided by CBS.